

1-1-2016

Pause for thought - Surgical Time Out: Before or after Painting & Draping. A Quality Improvement Project.

Margaret McHugh
Royal College of Surgeons in Ireland

Citation

McHugh M. Pause for thought - Surgical Time Out: Before or after Painting & Draping. A Quality Improvement Project. [MSc Thesis]. Dublin: Royal College of Surgeons in Ireland; 2016.

This Thesis is brought to you for free and open access by the Theses and Dissertations at e-publications@RCSI. It has been accepted for inclusion in Masters theses/dissertations - taught courses by an authorized administrator of e-publications@RCSI. For more information, please contact epubs@rcsi.ie.

— Use Licence —

Creative Commons Licence:



This work is licensed under a [Creative Commons Attribution-Noncommercial-Share Alike 3.0 License](https://creativecommons.org/licenses/by-nc-sa/3.0/).

Pause for thought - Surgical Time Out:

Before or after Painting & Draping.

A Quality Improvement Project

{Margaret Mc Hugh}

A Dissertation submitted in part fulfilment of the degree
of MSc Quality & Safety in Healthcare Management Institute of
Leadership, Royal College of Surgeons in Ireland

2016

Student ID: 14121034

Submission Date: 12/05/2016

Word Count: 16, 103

Facilitator: Mary McCarthy

Acknowledgements

This project would not have been possible without the support of my organisation; I would like to thank the C.E.O. for supporting this project and the consultants and staff who contributed their time, commitment and most importantly their trust. In particular, I would like to acknowledge our theatre manager Mary Doody for her determination and passion and Mary A Walsh for her patience and attention to detail.

Thank you to the programme directors at RCSI, Siobhán McCarthy and Steve Pitman and to my ALS facilitator Mary McCarthy for their wisdom and guidance.

To my new friends, thank you for the laughs and the encouragement.

To my old friends and my family, many thanks for your patience and sustenance while I knitted.

Table of Contents

Abstract	4
1.1 Introduction	5
1.2 Organisational Context	5
1.3 Rationale for selecting the Project	5
1.4 Aims and Objectives	7
1.5 Role of the student in the organisation and project	8
1.6 Organisational impact and expected outcomes	9
1.7 Potential threats to implementation	9
2 Literature Review	
2.1 Introduction	11
2.2 Search Strategy	11
2.3 Review Themes	11
2.3.1 Never Events	11
2.3.2 Universal Protocol	15
2.3.3 Checklists	19
2.3.4 Site Marking	22
2.4 Conclusion	23
3 Organisational Development Process	25
3.1 Introduction	25
3.2 Organisational Development	25
3.3 Change	26
3.4 Resistance to Change	27
3.5 Models for change	28
3.5.1 Lewins 3-Step Model	29
3.5.2 HSE Model of Change	31
3.5.3 Action Research cycle	32
3.6 Rationale for the chosen model	32
3.6.1 The Senior & Swailes Model of Change	32
3.7 Methodology	34
3.7.1 Present State	34
3.7.2 Future State	36
3.7.3 Gain Commitment to the Vision	36
3.7.4 Develop an Action Plan	36
3.7.5 Implement the Change	37
3.7.6 Assess & Reinforce the Change	38
3.8 Conclusion	38
4 Evaluation	39
4.1 Introduction	39
4.2 The Importance of healthcare evaluation	39
4.3 Models of Evaluation	40
4.3.1 Kirkpatrick's four-level evaluation model	40
4.3.2 The logic model	41

4.3.3	The CIPP (context/input/process/product) model	41
4.3.4	Methods and measures	42
4.3.4.1	Context evaluation	43
4.3.4.2	Input evaluation	49
4.3.4.3	Process evaluation	50
4.3.4.4	Product evaluation	52
5	Discussion & Conclusions	56
5.1	First do no harm	56
5.2	Where theory meets practice	57
5.3	Strengths of the Project	58
5.4	Limitations	59
5.5	Ethical considerations	59
5.6	Recommendations for future improvements	59
	References	60
	Bibliography	67
	Appendices	68

Abstract

Background: In recent years surgical errors have received increasing attention and so called 'never events' include wrong site/side/patient surgery. Both the Joint Commission and the World Health Organisation have sought to reduce the risk of these events occurring with the introduction of the Universal Protocol (Joint Commission International, 2004) and Guidelines for Safe Surgery: safe surgery saves lives (World Health Organisation, 2007). Despite these initiatives, surgical never events continue to occur.

Context: This Organisational Development (OD) project aimed to align the organisations 'Time Out' process with the WHO directive that 'Time Out' occurs immediately prior to knife to skin. Using action research based on the Senior & Swales (2010) OD model for change, the current situation was diagnosed through audit, informal interviews, internal data review, assessment of current literature and survey data of the practices in other private hospitals in Ireland. The future state which is envisioned is to never have a surgical 'never event' in our organisation. Commitment to our vision was gained through management sponsorship, stakeholder analysis, support of champions, presentations and discussions with surgeons and staff. Developing an action plan was the remit of the implementation team who agreed the PDSA methodology. The change was implemented through pilot of surgical procedures and was audited throughout the process. Evaluation found that there was a 6% decrease in the ability to confirm the patient identity and a 42% reduction in the visibility of the site mark. While overall the objectives of the project were achieved, feedback from surgeons and staff was that the proposed change increased the likelihood of 'wrong site surgery' and should not be implemented. However, opportunities for improvement in regard to scheduling of surgeries, confirmation of imaging and improved site marking practices were identified. Finally the writer concludes that further study is required on 'Time Out' and the apparent disconnect between theory and practice.

1.1 Introduction

The statement attributed to Professor Arthur Bloomfield (1888- 1962) that: ‘There are some patients that we cannot help; there are none whom we cannot harm’ (2004) recognised the possibility of healthcare practitioners causing patient harm well in advance of the seminal works of the Institute of Medicine (IOM, 1999).

Today’s healthcare is highly complex. Care is often delivered in a fast-moving, pressurised environment. Sometimes unintended harm occurs during a procedure or as a result of a clinical decision. Unfortunately sometimes the injury to the patient is life changing or at its worst, life ending.

Surgical errors have received increasing attention in recent years and some have been defined as ‘never events’. The term ‘never event’ was first introduced in 2001 by Ken Kiser, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors such as wrong-site surgery (Agency for Healthcare Research and Quality). Since then, both the Joint Commission and the World Health Organisation have sought to address this issue with the introduction of both the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery (Joint Commission International, 2004) and Guidelines for Safe Surgery: safe surgery saves lives (World Health Organisation, 2007). Despite these initiatives, surgical ‘never events’ continue to occur, albeit that evaluations of the WHO checklist have been positive (O’Connor *et al.*, 2013).

1.2 Organisational Context

The writer’s organisation is a 120 bedded private hospital which provides a wide range of elective medical and surgical services. The hospital currently admits 18,000 patients per annum, comprising 6,000 in-patients and 12,000 day-cases. The majority of patients are surgical, undergoing elective surgical procedures. The organisation was first accredited by Joint Commission International in 2005 and has retained its “Accredited Hospital” status since then.

1.3 Rationale for selecting the Project.

The Joint Commission International Accreditation (JCI) Standards for Hospitals mandates

that hospitals develop and implement a process for ensuring correct site, correct procedure and correct patient surgery (JCI, 2014). The writer's organisation continuously strives to maintain compliance with their accreditation standards.

Evidence-based practices are described in The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. The essential processes found in the Universal Protocol are:

- marking the surgical site;
- a preoperative verification process; and
- a time-out that is held immediately before the start of a procedure.

The World Health Organisation's Second Global Patient Safety Challenge: Safe Surgery Saves Lives addresses the safety of surgical care. The World Alliance for Patient Safety initiated work on the Challenge in January 2007.

The focus of the challenge is the WHO Safe Surgery Checklist. The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anaesthesia (Sign in), before the incision of the skin ('Time Out') and before the patient leaves the operating room (Sign out) (WHO, 2007). In this regard, the checklist goes further than the JCI standards in stating that the 'Time Out' is conducted immediately prior to knife to skin. The current practice in the writer's organisation is to conduct 'Time Out' prior to painting and draping of the patient and this practice was viewed by JCI at time of last survey as not in line with the direction of the WHO.

In Ireland, the timing of surgical 'Time Out' is less well defined. The national policy and procedure for safe surgery states that, while before skin incision is the recommended time to complete the 'Time Out' based on the WHO recommendations, if individual organisations wish to perform the 'Time Out' prior to skin preparation and draping the patient, this policy may be adapted locally (Quality and Patient Safety Directorate, 2013).

This poses a challenge for the writer's organisation. The World Health Organisation

direction is that 'Time Out' occurs immediately prior to knife to skin and therefore it is the expectation of our accrediting body that we align ourselves to the Surgical Safety initiative. As it is also a JCI International Patient Safety Goal (IPSG) and any 'not met' in the measurable element of an IPSG results in an automatic focused survey, the organisation is very keen to progress change on this issue. However nationally, the practices in regard to the timing of 'Time Out' are less clear and it will be vital to the success of this proposed change that it can be clearly demonstrated that the change will indeed lead to an improvement in patient safety.

1.4 Aims and Objectives

The overall aim of this proposed quality improvement is to align the organisations surgical 'Time Out' process with the World Health Organisation (WHO) directive by March 2016 ensuring that 'Time Out' occurs immediately prior to knife to skin in 100% of surgeries.

In order to achieve this aim, the following objectives were identified:

Objective 1: To complete a stakeholder analysis by October 2015 and agree an implementation team.

This analysis will enable the writer to identify everyone with a concern or interest who needs to be involved in the planned improvement (Appendix 2).

Objective 2: To conduct an observation audit of 'Time Out' practices by September 2016 to identify the current situation.

The purpose of this audit is to establish a baseline, assess present practices and identify opportunities to improve

Objective 3: To conduct interviews with both surgeons and staff on the present state and their vision for the future by November 2015.

Conducting informal interviews with both surgeons and clinical nurse managers will identify their views and concerns and possible resistance to change.

Objective 4: To complete a review of the literature by December 2015

The purpose of the literature review is to provide stakeholders with a succinct, objective

and logical summary of the current knowledge on 'Time Out'. It will also have an important function in evaluating current practice and making recommendations for policy development and change.

Objective 5: To conduct a survey of other private hospitals by March 2016 to ascertain their practices in regard to 'Time Out'.

Establishing practices in regard to 'Time Out' in other private hospitals will give context to the organisations own practices in this regard.

Objective 6: To implement change of practice using the Plan, Do, Study, Act (PDSA) quality improvement cycle by March 2016.

This will involve piloting the introduction of a further secondary 'Time Out' immediately prior to knife to skin and measuring both to ascertain compliance with criteria for 'Time Out'.

Objective 7: To roll out the improvement programme as evidenced by:

- Policy revision and approval by March 31st 2016
- Education of all relevant staff on change of practice by March 31st 2016

See Appendix 1 for Project Plan

1.5 Role of the student in the process.

One of the writer's main responsibilities in the organisation is to implement best practices, quality improvement initiatives and promote patient safety. During the hospital accreditation survey in 2014 there was detailed discussion with the survey team in regard to the timing of 'Time Out' and it was agreed that as Quality lead, the writer would plan to implement a change in this process prior to the next accreditation survey in 2017. This will be done with the support of the relevant stakeholders and the process will be facilitated by the use of quality improvement tools including PDSA, brainstorming, mind mapping and stakeholder analysis.

1.6 Organisational impact and expected outcome(s).

1.6.1 Organisational impact:

It is anticipated that this change project will strengthen the safety of the surgical practices and decrease the likelihood of wrong site, side or patient surgery.

1.6.2 Planned Outcome:

100% of surgical patients will have 'Time Out' conducted immediately prior to knife to skin in accordance with the WHO Surgical Safety initiative.

1.7 Potential threats to implementation.

The writer's organisation originally introduced the surgical 'Time Out' in 2006, becoming one of the first hospitals in the country to do so. At the time none of the other local hospitals had implemented a similar process and as many of the consultants worked in more than one location, there was initially strong resistance to its implementation. Highlighting some of the near misses which had occurred, identifying champions among the surgeons and ensuring buy in by the nursing staff were key to its successful introduction.

Through this process much time and effort was expended on ensuring that 'Time Out' was consistently performed and took place only when the whole team was present. The timing of 'Time Out' seemed less significant and evolved into the present practice of conducting 'Time Out' prior to painting and draping because it was perceived to be the safest time to do so.

Changing the perceptions of Consultants that 'Time Out' is best conducted after the patient is draped will be challenging, as will getting buy in from nursing staff. From the writer's experience, changing a practice which has been embedded will require the weight of empirical evidence and the ability to demonstrate to consultants and staff that the change will in fact further decrease the likelihood of wrong site, side or patient surgery.

Chapter two will review the available literature on surgical 'Time Out' and provide a critique

of the literature in this area. It will outline the implications for the project and offer evidence to support the rationale for the change. It will conclude with a brief overall summary of the findings from the literature.

Chapter three details the Organisational Development methodology structured using the Senior & Swailes model (2010) for change while incorporating a PDSA cycle. Chapter four includes a brief discussion on the importance of healthcare evaluation, outlines the methods of evaluation employed and details the analysis carried out. The writer has identified the need to evaluate the following:

- 1) Results of observational audit of 'Time Out'.
- 2) Findings from staff and consultant interviews prior to the introduction of the change project
- 3) Results of a survey of private hospitals on their practices in regard to 'Time Out'.
- 4) Audit results to demonstrate whether this change effectively meets the requirements for a complete 'Time Out'.
- 5) Feedback of staff and consultants on the change.

Chapter five draws together the findings from this project, the authors experience in introducing the change and its relationship to the literature. It concludes with a discussion of the impact of this project on the organisation and explores recommendations for future improvements.

2. Literature Review

2.1 Introduction

This literature review evaluates the available evidence in regard to surgical 'Time Out' and the World Health Organisation (WHO) Surgical Safety Checklist.

2.2 Search Strategy

A systematic literature search was conducted of MEDLINE at EbscoHost, CINAHL, EMBASE, Web of Science and the Cochrane Database using a search strategy developed in collaboration with a medical librarian. The search strategy included studies published from January 2006 to March 2016, and used a combination of medical subject headings and keywords related to "surgical", "Time Out", "surgical pause", "medical errors prevention and control", "operative standards", "guidelines", "wrong site surgery", "site marking", "never events" and "checklists". Google scholar was also used to follow references found in the bibliographies of the selected articles. This allowed the writer to identify seminal articles in this area. Seventy two articles were considered relevant to the themes identified.

2.3 Review Themes

The themes for the literature review were identified through interview with both consultants and staff and preliminary searches by the writer. The themes identified as most relevant to the change project were: Never events/Wrong patient, site or side surgery, the Universal Protocol for correct patient, site or side surgery, Checklists and Site marking.

2.3.1. Never Events – Wrong patient, wrong site, wrong side surgery

"Primum non nocere" (first do no harm): Hippocrates (c. 460 BC-377 BC).

With more than 200 million surgical procedures carried out worldwide each year, reports reveal that adverse event rates remain unacceptably high, despite a number of global safety initiatives over the past decade (Kim *et al.*, 2015). The term wrong-site surgery refers to any surgical procedure performed on the wrong patient, wrong body part, wrong side of the body, or at the wrong level of the correctly identified anatomic site (JCAHO, 2004). It represents some of the worst medical errors that patients and surgeons experience (Seiden & Barach, 2006).

Since the late 1990s there have been a number of interventions identified to try and eliminate the possibility of performing wrong site surgery. These included the 'Sign Your Site' campaign, advocating that orthopaedic surgeons initial the surgical site before surgery and 'SMaX' guidelines for signing, marking, and ensuring availability of radiography before surgery (Ragusa *et al.*, 2016). In 2004, the Joint Commission on Accreditation of Healthcare Organization developed the Universal Protocol which included preoperative verification of the patient and the site, surgical site marking and a 'Time Out' before any planned surgical procedure (JCAHO., 2004). The Universal Protocol became mandatory for all hospitals accredited by the Commission.

Further initiatives include the '100,000 Lives Campaign' (2005/2006) and subsequent '5 Million Lives Campaign' (2007/2008) by the Institute for Healthcare Improvement (IHI), the Surgical Care Improvement Project (Kim *et al.*, 2015). In 2009, the World Health Organization (WHO) established the WHO Safe Surgery Checklist. This checklist was a product of the WHO Second Global Patient Safety Challenge 'Safe Surgery Saves Lives' campaign (WHO, 2009). The checklist identifies 3 stages: (1) the "sign-in" phase, before the induction of anaesthesia; (2) the "time-out" phase, before the surgical incision; and (3) the "sign-out" phase, before the patient leaves the operating room (WHO, 2009).

Also in 2009 the Joint Commission expanded the Universal Protocol to include availability of imaging and to ensure that required documents and specialised medical technology are on hand, correct and functional. They further prioritized implementation of the Universal Protocol by designating it as a Patient Safety Goal (Ragusa *et al.*, 2016).

These strategies were driven by the desire to reduce wrong patient, site, or side surgery and also to save lives and improve surgical patient outcomes. They are built on the premise that while a highly protective layer of staff and processes protects the patient from harm, described by Reason (1990) in the swiss cheese model where opportunities for error occur when the holes in many slices briefly align. These strategies try to minimise the likelihood of such alignment. Unfortunately, despite these efforts, statistics for wrong-patient, wrong-site, wrong-procedure events reviewed by the Joint Commission shows little

improvement in the number of events reported (Joint Commission, 1995-2015). (Appendix 3) Recurring reports highlight the continued occurrence of wrong-site and wrong-patient procedures in the United States (Stahel, 2014).

So why are these events still happening? Following wrong patient, site or side surgery, hospitals invariably conduct a root cause analysis to identify, diminish and where possible, eliminate the root and contributory causes of the event. This intense investigation usually results in a set of actions or programs intended to prevent a reoccurrence (Michaels *et al.*, 2007). In a 2009 study of actual and near miss wrong site occurrences, Blanco *et al.* (2009) found that: in 63% of actual wrong site occurrences, the verification was not done; in 61%, the 'Time Out' was not done; and in 56% of occurrences, the surgical mark was not visible during 'Time Out'. Another study identified transcription errors in documents and omitting steps in verification, as main areas of vulnerability (Abecassis, 2015).

Seiden (2006) identifies confusion regarding laterality as a cause of wrong site or side occurrences. Surgeons are used to their 'right' being their patient's 'left', when facing a patient. However it can be very challenging during surgery in the theatre, when the patient is covered in sterile drapes or the patient's position is changed during the procedure, perhaps rotated onto one side with limbs flexed. It can necessitate considerable mental effort for the surgeon to identify right from left. It is not surprising that laterality could be subject to error, especially in a distraction rich environment (Seiden, 2006). The Pennsylvanian Patient Safety Authority encourage communication from all team members on this issue and point out that the anaesthetist may be the only person in the theatre whose view of the patient is the same as their physical orientation (Authority, Pennsylvania Patient Safety, 2008).

Wrong patient surgery highlights the need for correct patient identification; ensuring wristbands are accurate and used correctly during the preoperative verification process and 'Time Out' (Blanco, 2009). It is being increasingly recognized that involvement of the patient in the verification process can decrease the likelihood of wrong site or person surgery, but patient factors such as language barriers, fear or disease acuity have been known to contribute to error (Hanchanale *et al.*, 2014).

DeVine *et al.* (2010) identified such contributing factors to wrong site surgery as: incorrect patient positioning; incorrect preparation of operative site; patient providing incorrect information; incorrect patient consent; lack of site markings; surgeon fatigue; multiple procedures on same patient; unusual time pressures; unusual patient anatomy; and poor communication.

A frequently reported cause of wrong-site surgery across analyses identified communication problems such as: miscommunications; missing information; staff not speaking up when they noticed that a procedure targeted the wrong side; and a surgeon ignoring those who questioned laterality (Hempel *et al.*, 2015). The Pennsylvania Patient Safety Authority highlight the importance of individuals in the surgical team feeling confident to question the decision of any other team member concerning issues regarding patient identity, procedure, site, side and availability of equipment or implants (Authority, Pennsylvania Patient Safety, 2008). Lee *et al.* (2013) emphasise the need to eliminate the hierarchy in operating rooms, so that all staff feel free to speak up when a patient safety issue is noticed. Others focus on the positive impacts of medical team training on theatre team communication, resulting in the avoidance of undesirable events through increased preoperative briefings, postoperative debriefings, improved perceptions of teamwork and patient safety (Neily, 2011).

In more recent years, attention has widened to outside of the operating theatres and to a more expansive review of the complete patient pathway for surgery. Analysis of the patient's pathway has highlighted potential errors in the administrative and medical care. An early error in scheduling detail or an incorrect x-ray report can be the starting point for a wrong diagnosis (Abecassis, 2015; Hadjipavlou & Marshall, 2013).

A study conducted by Paull *et al.* (2015) demonstrated that 16% of wrong surgery events were due to errors that occur upstream or downstream to the universal protocol highlighting the need to enlarge the safety net. Between 2004 and 2013, the Pennsylvania Patient Safety Authority received 541 reports of wrong site procedures. A review of these reports reveals that 11% experienced wrong site surgery due to the facility receiving incorrect or incomplete information from the surgeon's office (Clarke, 2014). Cobb (2012) argues that the first line of defence against error is the preoperative verification process

which unfortunately can be flawed by mistakes weeks or even months before the planned surgery. Most hospitals do not cross check the scheduled procedure with the surgeon's history and physical and other preoperative notes, thus failing to make this first step of the process fool proof (Cobb, 2012).

There are significant difficulties in conducting research designed to evaluate the effectiveness of interventions intended to reduce wrong patient, site or side surgeries. Despite its potentially devastating consequences and given the relatively low incidence of these events, large numbers of participants would be required to show a significant effect from any intervention (Algie, 2015). Perhaps as suggested by Hollnagel *et al.* (2015), the focus of future investigation should not be on what went wrong but on understanding how things usually go right. This move from Safety-1 to Safety-11 (Hollnagel *et al.*, 2015), is a paradigm shift from ensuring as few things as possible go wrong to ensuring as many things as possible go right. If a surgical never event occurs in approximately one in every 17,000 operations, that means that in 16,999 operations the processes worked. This lends weight to the notion that healthcare organisations have huge opportunity to learn from what has gone well and from when never events have not occurred (Moppett & Moppett, 2016).

2.3.2. Universal protocol

The Universal Protocol is a three-step process which includes verification, site marking and 'Time Out' (JCAHO, 2004). It was launched as a standard by the Joint Commission with the intent of reducing the occurrence of wrong-site and wrong patient surgery (Stahel, 2014).

Step 1. Verification:

This step consists of confirming the correct patient, site and procedure at every stage from the time a decision is made to operate to the time the patient undergoes the operation.

Verification takes place:

- when the procedure is scheduled;
- at the time of admission or entry to the operating theatre;
- any time the responsibility for care of the patient is transferred to another person and:

- before the patient leaves the preoperative area or enters the procedure room.

Verification should involve the patient and requires correct identification of the patient and confirming the site, laterality and procedure by checking the patient's records and radiographs. This is an active process that must include all members of the team involved in the patient's care (JCAHO, 2004). The rationale for conducting a pre-operative verification is to reduce risk. Each patient is unequivocally identified by an identification bracelet which includes the patient's name, date of birth and medical record number. The consent form is checked to ensure that the procedure outlined is what is intended. The surgical site mark is also confirmed with the patient before they are brought into the operating room (Stahel, 2014).

Step 2. Site Marking:

The Universal Protocol states that the site or sites to be operated on must be marked in cases of laterality, multiple structures (e.g. fingers, toes, ribs) and multiple levels (e.g. vertebral column). The protocol stipulates that marking must be:

- at or next to the operative site; non-operative sites should not be marked;
- unambiguous, clearly visible and made with a permanent marker so that the mark is not removed during site preparation;
- made by the surgeon performing the procedure and;
- completed, where possible, with the patient's involvement. (JCAHO, 2004).

The Joint Commission views failure to engage the patient as one of the causes of wrong-site surgery (JCAHO, 2004). However pitfalls in surgical site marking represents an important underlying root cause contributing to the risk of wrong site surgery (Stahel, 2014). These pitfalls include: the delegation of site marking to someone not involved in the surgery; using an X to mark the correct site; marking the wrong site based on incorrect information; the use of non-permanent markers; and imprecise site marking (Stahel, 2014).

Step 3. 'Time Out':

The "Time Out" or 'surgical pause' is a brief pause just before starting the procedure to confirm the patient, the procedure and the site of operation. It is also an opportunity to ensure that the patient is correctly positioned and that any necessary implants or special

equipment are available. The Joint Commission stipulates that all team members are actively involved in this process. Any concerns or inconsistencies must be clarified at this stage. The checks during the 'Time Out' must be documented, potentially in the form of a checklist, but the universal protocol leaves the design and delivery to individual organizations (JCAHO, 2004). The 'Time Out' also serves to foster communication among team members (WHO, 2009). Key parameters for a successful 'Time Out' include a standardised process, full team participation, suspension of routine activities and the process repeated where a secondary procedure is being performed on the same patient. Stahel (2014) promotes a two-tiered process, referring to the verification as an 'awake 'Time Out' followed by a repeat 'Time Out' immediately prior to knife to skin, with the intent of avoiding painting and draping of the wrong surgical site.

Despite widespread implementation of the universal protocol in the United States, this standardised practice has failed to prevent never events from happening (Stahel, 2014). In a systematic review DeVine (2010) found that there was no literature to substantiate the effectiveness of the universal protocol for decreasing the rate of wrong site, wrong level surgery. During a six-and-a-half-year study period before and after implementation of the universal protocol, a total of 25 wrong-patient and 107 wrong-site procedures were identified. The main root causes leading to wrong-patient surgery were errors in diagnosis (56%) and in communication (100%), whereas wrong-site occurrences were related to errors in judgment (85%) and the lack of performing a surgical 'Time Out' (72%). It appears that despite the widespread mandatory use of a strict protocol-driven approach the universal protocol does not keep patients safe (Stahel, 2014).

This perhaps adds weight to the Paull *et al.* (2015) concept of errors upstream and downstream to the universal protocol. This study identified that some errors can occur before the beginning of the universal protocol process on the day of surgery (upstream) e.g. incorrect details forwarded from doctors office, mislabelling of images and selection of wrong lens, or after the completion of the time-out (downstream) e.g. wrong procedure performed.

No amount of adherence to the universal protocol will prevent the surgeon getting distracted mentally and drifting from the intended procedure. Examples include doing a

total hysterectomy and bilateral salpingo-oophorectomy when the intended procedure was a simple hysterectomy, or performing a tonsillectomy and adenoidectomy when the intended procedure was an adenoidectomy (Clarke, 2015). The ability of the universal protocol to prevent wrong surgery can be strengthened by confirming all preoperative documents with their primary sources for the critical information. In addition, everyone on the team should maintain a memory of the intended procedure and monitor what is being done throughout the surgery, not just during the 'Time Out' (Clarke, 2015).

As previously stated, events such as wrong-site operations are too rare to measure as rates. Instead, hospitals often measure safety and quality protocol compliance through peer audits, questionnaires, or chart audits. While audits and questionnaires will yield some data, these strategies alone do not capture compliance outside of what is documented (Logan *et al.*, 2012). Areas of concern include surgeon and staff behaviour, poor communication, room traffic and distractions, and the lack of cultural strategies to prevent the errors (Conrardy *et al.*, 2010).

Based on an integrative review of literature, Conrardy *et al.* (2010) argues that the current state of the science for implementation of the universal protocol varies from organisation to organisation. Variations included different adaptations of the universal protocol elements and inconsistent compliance with the actual process. They determined that organisations that were successful in the implementation of the universal protocol had the following elements: a multidisciplinary team approach throughout the universal protocol implementation process; active staff and patient participation; supportive hospital management; and dynamic communication that promotes a healthy work environment (Conrardy *et al.*, 2010).

Stahel (2014) argues that the continuing expansion of the 'Time Out' to include secondary safety issues, such as antibiotic and venous thromboembolism prophylaxis ('expanded' 'Time Out'), has diluted the intent of the universal protocol in its core essence and likely contributes to decreased compliance and credibility of the protocol related to the 'buy-in' by the surgical team.

'Operating on a human being is an extraordinarily complex and orchestrated task that requires attentiveness to detail and situational awareness by all team members. Checking a box is no substitute for critical thinking' (Wang & Ser, 2014 p.15).

Surgical Safety Checklist (First Edition)		
<p>Before induction of anaesthesia</p> <p>SIGN IN</p> <ul style="list-style-type: none"> <input type="checkbox"/> PATIENT HAS CONFIRMED <ul style="list-style-type: none"> • IDENTITY • SITE • PROCEDURE • CONSENT <input type="checkbox"/> SITE MARKED/NOT APPLICABLE <input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED <input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING <p>DOES PATIENT HAVE A:</p> <p>KNOWN ALLERGY?</p> <ul style="list-style-type: none"> <input type="checkbox"/> NO <input type="checkbox"/> YES <p>DIFFICULT AIRWAY/ASPIRATION RISK?</p> <ul style="list-style-type: none"> <input type="checkbox"/> NO <input type="checkbox"/> YES, AND EQUIPMENT/ASSISTANCE AVAILABLE <p>RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?</p> <ul style="list-style-type: none"> <input type="checkbox"/> NO <input type="checkbox"/> YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED 	<p>Before skin incision</p> <p>TIME OUT</p> <ul style="list-style-type: none"> <input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE <input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM <ul style="list-style-type: none"> • PATIENT • SITE • PROCEDURE <p>ANTICIPATED CRITICAL EVENTS</p> <ul style="list-style-type: none"> <input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS? <input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS? <input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS? <p>HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?</p> <ul style="list-style-type: none"> <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE <p>IS ESSENTIAL IMAGING DISPLAYED?</p> <ul style="list-style-type: none"> <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE 	<p>Before patient leaves operating room</p> <p>SIGN OUT</p> <p>NURSE VERBALLY CONFIRMS WITH THE TEAM:</p> <ul style="list-style-type: none"> <input type="checkbox"/> THE NAME OF THE PROCEDURE RECORDED <input type="checkbox"/> THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE) <input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME) <input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED <input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

In 2009, a major study by the WHO in conjunction with the Harvard School of Public Health demonstrated a significant improvement in surgical morbidity from 11% to 7% and mortality from 1.5% to 0.8% (Haynes *et al.*, 2009). However a more recent study in Ontario, Canada found that there was no significant difference in mortality rates or complication rates following surgical checklist implementation (Urbach *et al.*, 2014). A change effort such as the introduction of the WHO checklist can only be successful when there is a link drawn between the ‘explaining why’ and the individual's perception of what is of value (Rydenfält *et al.*, 2013).

Some commentators believe that the emphasis on checklists is a distraction from how safer care is really achieved. Bosk *et al.* (2009) argues that widespread deployment of checklists without an understanding of how or why they work could be a potential threat to patients' safety and to high-quality care. Wang & Ser (2014) believes that while there is no harm in spending one to two minutes ensuring that the constituents of a successful procedure are in order, reliance on checklists beyond this should be avoided.

O'Connor *et al.* (2013) found that the overall attitudes towards the checklist from respondents were overwhelmingly positive. Another survey of 704 theatre staff also showed that a large majority of the responders thought that confirmation of patient identity, correct procedure, correct side and checking of allergies or contagious diseases were 'very important' before the start of surgery (Nilsson *et al.*, 2010). An interview study with operating room staff conducted across 10 hospitals in UK identified the following as crucial to successful implementation of the checklist: modification of the initiative to the local context; education around the evidence base; training on the practical application; identifying champions; ensuring buy-in from senior clinical staff; involvement of management; and auditing and feedback of data to staff (Russ *et al.*, 2015).

All members of the theatre team must be involved in the checklist procedure so that it is a true multidisciplinary intervention. Anaesthetists' attitudes towards the application of the checklist have been found to be less positive than those of surgeons or nurses. O'Connor *et al.* (2013) recommends that discussions are held with anaesthetists in order to identify a time in which they are able to be involved in the checklist process.

Lingard (2008) identified barriers that threaten the consistent uptake of a new communication routine like the briefings outlined in the checklist. These include the notion of individual excellence; chronic staff shortages, educational duties, and economic pressures. When poorly used, the checklist can potentially have a harmful effect on safety and teamwork in the operating theatre (Lingard, 2008). Surgeons and anaesthetists can sometimes give the impression that the checklist is delaying time, putting pressure on nurses to ensure that items are covered quickly. Dismissive replies (affirmative and inaccurate) often go unchallenged by other staff (Vats *et al.*, 2010). In a direct observation study, the time-out section of the checklist was usually attempted, but the sign-out section

was not. Three simple measures were used to assess how well the time-out was performed, and satisfactory performance on all three measures occurred in only 38.5 % of observed operations (Pickering *et al.*, 2013).

Training programmes represent positive first steps in providing surgeons in Ireland with the teamwork knowledge and skills required to effectively lead a surgical team. However, a single training course, completed once in an individual's career is unlikely to result in a sustained cultural shift. There is a need for continuous reinforcement of good teamwork behaviours in the operating theatre, as well as the involvement of other members of the surgical team (O'Connor *et al.*, 2012). Allowing teams to customise the implementation of evidence locally, and challenge assumptions about whom has relevant knowledge, who counts as an expert, and who is able and ought to act to improve safety will greatly enhance the adoption of these patient safety measures (Bosk *et al.*, 2009).

The surgical safety checklist with its suite of actions goes beyond the universal protocol and includes measures aimed at reducing surgical complications and mortality as well as wrong site surgery (WHO, 2009). A survey of staff attitudes toward the introduction of 'Time Out' showed that >90% of theatre team members believed that it increases patient safety (Rydenfält *et al.*, 2013). However the direction that "Time Out" should be conducted immediately prior to knife to skin is not without its challenges. Some staff pointed out the futility of checking a patient's identity when "Time Out" occurs after painting and draping as the name bands cannot be accessed without compromising sterility. Some teams have tried to perform the time-out checks before the patient is draped, but this may also prove challenging because this period is often the busiest with staff doing tasks away from the patient (Vats *et al.*, 2010).

There is no question that the right checklist, with the right design and implementation, can be used enthusiastically by staff and can be extremely effective. But, unless attention is paid to the more complex narrative for how they emerged in other industries, including the changes required to culture, teamwork and design, there is little chance of realising similar benefits in healthcare (Catchpole & Russ, 2015).

2.3.4 Site marking

Site marking has, since the late 1990s been identified by orthopaedic groups, the Joint Commission, the Institute for Healthcare Improvement and the WHO as crucial to reducing the risk of wrong site/side surgery (Kim *et al.*, 2015; Ragusa *et al.*, 2016). In a study of 28 surgeons' ability to identify the correct side in procedures involving laterality without a site mark, the surgeons correctly identified the operated side in 76.5% by patients name and in 87% by looking at patients' faces, illustrating the likelihood of error in the absence of a site mark (Pikkel *et al.*, 2014).

Yet in a systematic review of wrong site surgery, Abecassis (2015) found thirteen studies that identified the surgical-site marking process in and of itself as the point of failure. Failings included: ambiguous markings; markings being washed off during prepping or transferred onto another part of the body; the mark being covered after prepping; and the patient confirming the wrong site.

One of the failures outlined is the possibility of the site mark being subject to fading or erasure during skin preparation. Despite a lack of consensus on the best skin preparation solution, patient safety experts recommend the use of chlorhexidine-based solutions for infection control purposes as surgical skin preparation agents (Thakkar & Mears, 2012). However in a randomized clinical trial they found that chlorhexidine-based skin preparation solutions erase surgical site markings more frequently than does an iodine-based solution. The removal of surgical site markings creates a major problem for performing an accurate 'Time Out' by the surgeon and the team, in addition to being an essential concern for patient safety (Thakkar & Mears, 2012). Furthermore, because the markings are often erased by the prep, the team may assume that the mark has been removed with the surgical prep and fail to stop the procedure on the wrong extremity (Cobb, 2012). A comparative study assessing the clarity and resistance of commercially available pens for site marking found a wide variation between the clarity of marks made by the different pens, and also a wide variation in the resistance to skin preparation (Sim *et al.*, 2016).

In a prospective audit of 500 surgical markings for elective procedures conducted between 2008 to 2009 in a UK hospital, only 59% of site markings were visible

post-surgical draping. In the remaining cases, the mark could not be seen after draping, defeating the purpose of marking and increasing the risk for wrong site surgery (Masud *et al.*, 2010). While Thakkar & Mears (2012) identifies performing the surgical time-out before skin preparation as a possible remedy to this issue, he states that moving the timeout to any time other than immediately before the surgical incision creates other opportunities for misidentification. Unfortunately they fail to expand on what those opportunities are.

One reason for surgeon's reluctance to mark too close to the proposed surgical site is the concern in regard to contaminating the surgical site. Sim *et al.* (2008) argues that the risks of wrong-site surgery should always be balanced against infection transmission risk. The practice of surgical site marking with non-sterile marker does not affect the sterility of the surgical field. Surgeons should strongly enforce the necessity to mark the surgical site as an effective component in preventing wrong site/side surgery (Zhao *et al.*, 2009).

2.4 Conclusion

This review has identified a number of interventions introduced in order to eliminate the possibility of performing wrong site surgery. These included the: 'Sign Your Site' campaign; 'SMaX' guidelines; Universal Protocol; '100,000 Lives Campaign'; '5 Million Lives Campaign'; and the WHO Safe Surgery Checklist. Notwithstanding these interventions, incidence of wrong-patient, wrong-site, wrong-procedure events shows little improvement. Opportunities for error identified by the literature include inaccurate operating room scheduling, poor patient verification on the day of surgery, incorrect or poor site-marking practices, not being able to identify the patient and/or site mark during the time-out process and mistaken clinical verification of imaging.

Underlying root causes identified include poor communication, miscommunication, missing information, staff not speaking up and the hierarchical nature of the operating room. The notion of upstream and downstream errors challenges teams to look more closely at the patient pathway and identify opportunities for narrowing the margin for error. The current approach to patient safety, labelled Safety I, a 'find and fix' model is too linear a model for such a complex process as healthcare.

Focus needs to switch to what is known as Safety II: a proactive effort to enable things to

go right more often. A proactive safety management concentrates on how everyday performance usually succeeds rather than on why it seldom fails, and actively attempts to improve the former rather than simply preventing the latter.

3. Organisational Development Process

“If you want to truly understand something, try to change it” ~ Kurt Lewin (1890-1947)

3.1 Introduction

Against a background of spiralling technological advancements, an increasingly informed workforce and the fluidity of accepted work practices, change is now an ever-present feature of organisational life (Burnes, 2004). However while the need for change is recognised, international studies indicate that over 70 per cent of all major change initiatives fail to reach intended objectives (Isaksson *et al.*, 2011).

The aim of this organisational development project was to implement a planned change of the organisations surgical ‘Time Out’ process using an OD model for change. In this chapter, an overview of Organisational Development is provided as well as what constitutes planned and emergent change and what causes resistance to change. Models for change are reviewed and the rationale for deciding on a change model will be explained. Methodology and quality tools used are reviewed including the use of the Plan, Do, Study, Act (PDSA) cycle. Assessment and reinforcement of the change is discussed including measurement tools for both hard and soft objectives.

3.2 Organisational Development (O.D.)

Change is a common activity where managers, change agents, and staff members cooperatively tackle a problem and reach a solution (Maes & Van Hootegeem, 2011). Organisational Development is planned change in an organisational context (French & Bell, 1999). The idea of OD is to raise the effectiveness of the organization by focusing on the performance of groups and teams. Behind Organization Development is a deep humanist and democratic conviction coupled with an emphasis on the advancement of the organization’s success (Maes & Van Hootegeem, 2011).

An OD approach enables the contribution of all those involved in the change, offering the opportunity to contribute to the continuous improvement process. It facilitates both top-down and bottom-up influences (McAuliffe & Van Vaerenbergh, 2006). Cummings and

Worley (2009) outline a number of distinguishing characteristics of the O.D. approach to change. These include:

- Emphasis on goals and processes as a means of improving capacity to change.
- Change that needs to be sustained over a significant period of time.
- It involves the organization as a whole as well as its parts.
- It is participative and has top management support and involvement.
- It involves a facilitator who takes on the role of a change agent
- It concentrates on planned change but as a process that can adapt to a changing situation.

(Senior & Swailes, 2010).

Organisation Development focuses on total system change. OD practitioners facilitate, collaborate, and learn with the system. An overarching goal is to make the organisation able to solve problems on its own by teaching the skills and knowledge of continuous learning. OD views system improvement as an ongoing process in the context of a constantly changing environment. It relies on an action research model with extensive participation by those involved (Senior & Swailes, 2010). What is distinctive about action research and OD is that both follow a cyclical process of consciously planning, taking action and evaluating the action, leading to further planning and so on. The second dimension is that both approaches are participative; members of the system actively contribute in the cyclical process. The action research approach is potent, engaging people in seeking ideas, planning, taking actions, reviewing outcomes and learning what works and doesn't work (McAuliffe & Van Vaerengergh, 2006).

3.3 Change

Change can be either planned or emergent (Maes & Van Hootegeem, 2011). Planned change refers to conscious and deliberate actions to improve the functioning of an organization. It begins from the premise that there is a logical and coherent way to solve problems. Clear objectives for change can be determined and programmed to be implemented in a systematic way (Senior & Swailes, 2010). Planned change is an iterative process of analysis, action, and assessment (Cummings & Worley, 2009). It is starting intentional actions with the objective of achieving a particular result. This type of change usually involves a change agent who consciously creates conditions for transforming a

current situation/process into a new reality (Maes & Van Hootehem, 2011).

The idea that all change can be planned ignores those unpredictable forces outside the remit of organisations management. Emergent change evolves from variations when people deal with occurrences, breakdowns and other opportunities in everyday work. Such changes can only arise by means of action, have no beginning or end and cannot be predicted or planned (Maes & Van Hootehem, 2011). However because of the highly participative nature of Organisational Development, it has the ability to implement planned change while at the same time taking account of emergent change through listening to all those involved in the change process (McAuliffe & Van Vaerenbergh, 2006).

3.4 Resistance to change

People are the key component in any change process and that which will determine whether the change succeeds or fails. Recognising this and investing in building their ability to meaningfully engage in the process is an essential element in any change process. With the recognition that change is an ever-present feature of the health care environment, this building of internal capacity to create an open environment that allows people to reflect on and learn from their mistakes and failures as well as their successes, is critical to the future of health care organisations (McAuliffe & Van Vaerenbergh, 2006).

Pugh (1993) refers to organisations as 'coalitions of interest groups in tension'. The systematic nature of an organisation, the structures and processes, the culture, politics and style of leadership are closely linked with the values and attitudes of those who work there (Senior & Swailes, 2010).

Central to the success of organisational change is the acceptance of the change by employees. Within this context, the work of Kubler-Ross (1973), who argued that all humans go through 5 stages of 'grief' (denial, anger, bargaining, depression and acceptance) when faced with a loss or change, has been seen as relevant and has been applied to the management of organisational change (Barnard & Stoll, 2010).

Kotter & Schlesinger (1979) identified the four most common reasons people resist change as: parochial self-interest; misunderstanding and lack of trust; different assessments; and

low tolerance for change. He argues that dealing with resistance involves education and communication, participation and involvement, facilitation and support, negotiation and agreement. Further methods may include manipulation and co-optation, explicit and implicit coercion (Kotter & Schlesinger, 1979). Where to strategically position effort depends on the amount and kind of resistance that is anticipated, the relationship of the initiator to the resisters, the information required for designing the change and the stakes involved (Kotter & Schlesinger, 1979).

French *et al.* (2011) suggest that in order to minimise resistance in such cases, the change agent should make sure that the people affected by the change know specifically how the change will satisfy the following criteria:

- Benefit: The change should be perceived as 'a better way'.
- Compatibility: The change should be compatible with the existing values of those being asked to change.
- Complexity: The change should be as easy as possible to understand and use.
- Triability: The change should be something that people can try and make adjustments throughout the process.

The assumption that resistance to change is an enemy and should be overcome has not gone unchallenged. McAuliffe & Van Vaerenbergh (2006) state that on the contrary, change agents should encourage participants to express reluctance to change and suggests that identifying reasons for resistance will enable agents to recognize real problems that must be solved and fears that key actors may have. This approach sits well with the participative nature of organisational development.

3.5 Models for Change

Kurt Lewin was one of the first to describe how to direct and control change. His three-stage model was the basis for most of present day planned change models (Burnes, 2004). He is best known for the development of field theory, group dynamics, action research and the three-step model of change (Batra *et al.*, 2014). It is argued that fusion of these themes is necessary to understand and create change and therefore should be viewed in their entirety rather than as separate models (Burnes, 2004).

Lewin's analysis stems from the conviction that individual behaviour is a function of the group environment or 'field'. He believed that individuals are influenced by group norms and pressure to conform and therefore target for change should be the behaviour of the group. Consequently group decision-making is crucial in effecting lasting behavioural change among group members (Batra, 2014).

An action research approach to change involves analysing the current situation, identifying the array of possible change solutions and choosing the one that is most appropriate (Burnes, 2004). Concurrently, there needs to be a recognised need for change, a realization by the group that change is necessary. Furthermore, success through action research involves buy in at a group level rather than individual level, which is consistent with the view about group behaviour being the target for change (Burnes, 2004).

3.5.1 Lewin's 3-Step Model

Lewin (1947) argued that a successful change project involved three steps:

Step 1: Unfreezing.

Lewin believed that the constancy of human behaviour was based on an equilibrium held together by an intricate field of driving and restraining forces. He argued that this equilibrium needed to be 'unfrozen' before old behaviour can be cast-off and new behaviour successfully accepted (Burnes, 2004). Expanding on Lewin's ideas, Schein (1996) argued that the key to unfreezing was to recognise that change was a profound psychological dynamic process. Those involved in change have to feel safe from loss and humiliation before they can accept new information and reject old behaviours.

Step 2: Moving.

Lewin believed that it was very difficult to predict a specific outcome from planned change because of the complexities involved. Instead, those involved in change should take into account all the forces at work and should identify and evaluate, on a trial and error basis, all the options available (Lewin, 1947). This is the learning approach promoted by Action Research. It is this iterative approach of research, action and more research which enables people to move from a less acceptable to a more desired set of behaviours

(Burnes, 2004). This is what Schein (1996) calls 'cognitive restructuring' which to be effective will require people to identify with their new roles.

Step 3: Refreezing.

Refreezing seeks to steady the group at a new equilibrium and to confirm that the new behaviours are relatively established. Refreezing recognises that new behaviour must be consistent with the rest of the behaviour and the personality and environment of the learner(s) or it will simply flounder and fail (Schein, 1996). This is why Lewin saw successful change as a group activity, because unless group norms and routines are also transformed it is difficult for the individual to sustain the changed behaviour. In organizational terms, refreezing often requires changes in culture, norms, policies and practices (Burnes, 2004; Cummings & Huse, 1989).

Critics of Lewin view his approach to change as simplistic, linear and outmoded. It has been criticised for ignoring issues such as organisational politics and conflict (Burnes, 2004). Senior and Swales (2010) in their critique of Lewin's model concentrate mainly on his concept of refreezing, seeing it as ignoring the turbulent environment of modern organisations and the need for continuous change.

Kotter & Schlesinger (1979) builds on Lewin's model and outlines eight steps to transforming an organization: to establish a sense of urgency about the need to achieve change; create a guiding coalition; develop a vision and strategy; communicate the change vision; empower broad-based action; generate short-term wins; consolidate gains; and anchor new approaches in the organisations culture (Appelbaun, 2011; Kotter, 1996; Smith, 2005;). It has been argued that Kotter's first step could be seen as a sub-process of unfreezing and that his final step interpreted as a sub-process of refreezing (Isaksson, 2011).

Integration of these eight steps in an orderly fashion is a significant part of Kotter's model albeit that the importance of maintaining this order is under investigated. Despite its lack of theoretical foundation this model has become very popular. It is viewed as intuitive and relatively easy to accept since it is based on real-life experiences (Appelbaun, 2011). Limitations of Kotter's model include the rigidity of the approach, the perception that all

steps may not be relevant to each change process and the criticism that the model is not detailed enough to provide help for difficulties that arise during change management (Appelbaun, 2011).

Bullock and Batten (1985) analysed over 30 change models and proposed a change model containing four stages: Exploration, Planning, Action and Integration. Every stage has a number of processes that transform the organization system from one state into another. They identify the process flow of planned change as: (1) interventions change (2) the target variables of the organization, which has repercussions on (3) the staff members' behaviour and in its turn on (4) the organization results. More recent models have been developed as cyclical models and although these models replicate similar phases and processes, they depart from earlier models by acknowledging the dynamic nature of change (Coghlan & Brannick, 2014; Health Service Executive, 2008; Senior & Swailes, 2010,).

3.5.2 HSE Model of Change:

The HSE Change Model pays particular attention to the people and cultural aspects of change. It is built on and reflects the following core principles:

- The needs of service users and local communities together with the interests of staff are at the core of the change process.
- Integration and a whole-system approach, focuses on connections, relationships and dependencies of the system.
- Collaboration between different teams/agencies and between national and local level.
- Active engagement and participation of services users and staff in the change process.
- Emphasis on partnership and team working
- Prioritising long-term sustainable change and improved organisational effectiveness.
- Transfer of knowledge and skill so that the system equips itself to manage change.
- Processes for organisational learning through regular feedback, measurement and evaluation at all stages of the change.

- Locating the responsibility to manage change at all levels of the system, individual, group and organisational and at local, area and national levels (HSE, 2008)

The HSE Change Model is cyclical and based on four stages of the project management lifecycle: initiation, planning, Implementation and mainstreaming. The model recognises that change must be approached as a continuous process in which all of the stages and steps are interrelated and influence each other (HSE, 2008). While it acknowledges that efforts spent in the early stages contribute significantly to the successful implementation of change, its lack of analysis of the current situation was the determinant factor in the writer not choosing this model.

3.5.3 Action Research cycle

The Action Research cycle by Coghlan & Brannick, (2014) involves four main steps: constructing, planning action, taking action and evaluating action. The stakeholders are engaged to construct what the issues are, action is planned, the plans are implemented and the outcomes are evaluated. Great emphasis is placed on collaboration at each step of the cycle and a concurrent reflective cycle is required to ensure action research about the action research cycle (Coghlan & Brannick, 2014). This model however fails to acknowledge the dynamic nature of change and the possibility that through the collaborative approach, the cycle may need to go back to a previous step before moving forward.

3.6 Rationale for the chosen model

3.6.1 The Senior & Swailes model of change:

Current theories of Organisational Development, built on the work of Lewin, recognise that change is a process that is not linear but complex and messy. It requires many loops back and forth from one stage of the process to another, thus recognising the dynamic nature of change (Senior & Swailes, 2010). The model for change chosen for this Organisational development project is the Senior & Swailes (2010) OD model for change (Figure 2).

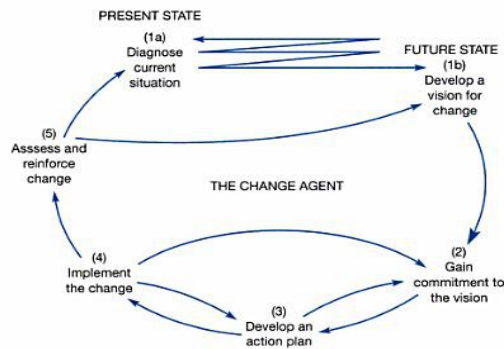


Figure 2: The Senior & Swailes OD model for change

This model been chosen for the following reasons:

- The model recognises that there is a need to diagnose the situation as it currently stands and develop a vision for the future. The connection between the current situation and the future state is dynamic, symbolised by a zigzag arrow. In reality, a change process is sometimes reactive, determined by perceived failings in the current state but can also be proactive, driven by an identified opportunity to improve, a vision which drives the organisation to reflect on 'what is' and look to 'what could be'
- Whatever the driver for change, gaining commitment to the vision for change is vital to the success of any project. The level of buy-in from stakeholders depends on the level of their involvement in the decision making process. Feeding back the findings from the analysis of the current state, starting a conversation about a future vision, listening to the organisation rather than 'shouting from the top' and recognising the strength of influence of both formal and informal group leaders are all vital to the successful implementation of a plan of action (Senior & Swailes, 2010).
- The model moves forward in its stages , developing an action plan, implementing the change and assessing and reinforcing the change, while all the time recognising that it may be necessary to move back to a previous stage during the cyclical process. This recognises the possibility of changes within changes occurring and therefore the need to iterate frequently around and across the different stages of the model (Senior & Swailes, 2010).
- This model for change recognises and places at its centre the change agent. This acknowledges the importance of those who act as facilitators of change. Moving people from current to future changed states is challenging and the skills and

competencies required may not reside in one individual and may require a team approach (Senior & Swailes, 2010). Placing the change agent at the centre of the model also reinforces the need for a collaborative approach to organisational development.

3.7 Methodology

3.7.1 (a) Present State –Diagnose current situation:

Diagnosing the current situation involves the data collection element of action research and the feedback of the results for discussion with the stakeholders who are concerned with, and involved in, the proposed change. Data gathering may include both the internal and external environment and forms the foundation for all subsequent stages of the OD cycle (Senior & Swailes, 2010).

The overall aim of this quality improvement was to align the organisations surgical ‘Time Out’ process with the World Health Organisation (WHO) surgical safety checklist, ensuring that it was conducted immediately prior to knife to skin. Any change in this process would therefore require the cooperation of both surgeons and theatre staff. In order to ensure buy-in, the following methods were employed to diagnose the current situation:

(i) Establishing the structure, processes and outcomes.

Donabedian (1988) stated that before measuring quality of care, detailed information is required to demonstrate the linkages between the structure of the setting in which care occurs, the processes and the outcomes of care.

In Donabedian’s model, structure includes material properties such as facilities, equipment, and resources, both financial and human, and the structure of the organisation. Process represents the act of giving care and includes the patient’s and practitioner’s roles. Outcome signifies the result of care on the health, wellbeing and safety of the patient. He asserts that good structure influences good processes, and good processes increase the prospect of good outcomes (Donabedian, 1988).

(ii) Observational audit of ‘Time Out’ process in each of the four theatres

Patient verification and the ‘Time Out’ process were audited on one surgical case in each of the four operating theatres to identify compliance with the organisations policy.

Observational audits have the advantage of being able to collect data on actual behaviour rather than reported behaviour (Cummings & Worley, 2014). Observation takes place in real time and enables the reviewer to measure compliance with the established structures and processes of the organisation.

(iii) *Interviews with both surgeons and staff on the present state and their vision for the future.*

The importance of involving stakeholders at the earliest opportunity is recognised and comprehensively addressed in the management of change literature (Coghlan & Brannick, 2014; Cummings & Worley, 2014; HSE, 2008; Kotter & Schlesinger, 1979; Lewin, 1947; McAuliffe & Van Vaerenbergh, 2006; Senior & Swailes, 2010). Interviews are a source of 'rich data', offer the opportunity to build rapport and display empathy (Cummings & Worley, 2009).

(iv) *A survey of other private hospitals to ascertain practices in regard to 'Time Out'.*

From discussions held with stakeholders, it became clear that to correctly diagnose the current state, it was necessary to try and identify what practices are in place in other hospitals. This was achieved by sending a survey tool to an identified sample of hospitals. The advantage of this data collection is that responses could be quantified and summarised and the results would perhaps inform the analysis of the planned improvement.

(v) *A review of current literature*

The purpose of reviewing the literature was to clarify and evaluate current literature on the proposed change. A recent study (Ahmad *et al*, 2015) demonstrated that the main learning styles of surgeons are reflector and theorist, 90% and 80% respectively and this is borne out through the writer's experience. A theoretical basis for the planned change was therefore extremely important and the search became a dynamic process as discussions with participants suggested differing search criteria.

(vi) *A review of internal data/reports on the potential for surgical error.*

The organisation culture is 'Just' and one of 'Safety' and staff are encouraged to report

good catches (near misses) and incidents and where available learning opportunities are identified. Previous patient safety events pertinent to the organisation can act as a motivator for change as they are tangible rather than abstract examples.

3.7.2 (b) Future state – Develop a vision for change

From the diagnosis of the current state comes the sense and vision of what needs to change. This progression does not wait for the diagnosis to be complete but rather begins to evolve early in the process and can bring demands for fresh information and create a sense that something new is being looked for (Senior & Swailes, 2010). In this project the close linkage between stages 1(a) and 1(b) resulted in a vision for change which did not define how the change was to be achieved but rather to define what our future should look like. That vision agreed was that the organisation will never have a wrong site/side never event.

3.7.3 Gain Commitment to the vision

The action research cycle of collecting, analysing data and feeding back to stakeholders is essential at all stages of a change process. Gaining commitment to change must include working with champions, group leaders and teams to identify and respond to their needs and concerns rather than simply informing them of the vision and the necessity for change (Senior & Swailes, 2010). This stage therefore involved the identification of champions, presentations to both surgeons and staff on never events (Appendix 4), observational audit findings (Appendix 5), the securing of management sponsorship and an analysis of stakeholders (Appendix 2).

3.7.4 Develop an action plan

Senior & Swailes (2010) identify a number of issues which are important in this stage of the process. The first is 'who' is to guide the planning and implementation of the change. The second is precisely 'what' needs to change to achieve the vision and the third is 'where' any intervention should take place. While the writer was the primary change agent of this project, through collaboration and constant communication, an implementation team was identified which effectively became a 'guiding coalition' (Kotter, 1996). To be effective Kotter identifies four key characteristics for this coalition; position power, expertise, credibility and leadership.

The implementation team therefore consisted of representation from hospital management, theatre management, clinical nurse managers, staff and surgeons, including the chair of the Theatre User Group. While the implementation team itself could not effect change, it could outline what was to be done by whom and with what kind of involvement from others (Senior & Swailes, 2010). Responsibilities were assigned and the methodology of PDSA and associated action plan was agreed.

3.7.5 Implement the change

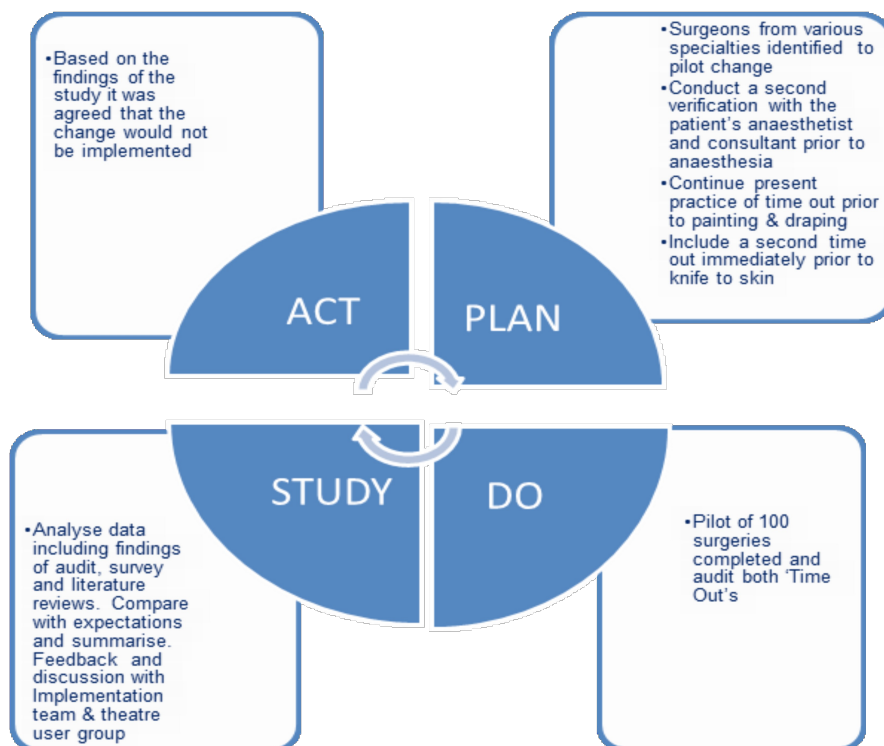


Figure 3 – PDSA Model

Plan:

Develop a plan to test out the cycle (who, what, where, when)

Who: Eight consultant surgeons from four specialties, General, Ophthalmic, Orthopaedic and Plastic surgery agreed to participate in the pilot.

What: - Conduct a secondary verification with the patient's consultant and anaesthetist when available before the patient is anaesthetised.

- Conduct a second 'Time Out' immediately prior to knife to skin on surgical patients whose procedure involved laterality, multiple structures (e.g. fingers, toes, ribs) and multiple levels (e.g. vertebral column) to ensure that the operation takes place on the correct patient and the correct side and site.

Where: Theatres 1, 2, 3, 4

When: Commence on Monday 1st February until 100 surgeries have been completed.

Do:

Carry out the change on a small scale (pilot), document any problems and collect data. See Audit tool (Appendix 6)

Study:

Analyse data, compare with expectations and summarise. Secure feedback from those involved in the pilot and present to implementation team.

Act:

Make changes as needed and decide whether improvement can be implemented.

3.7.6 Assess and reinforce the change.

Senior & Swailes (2010) contest that change is an evolving process and must concern itself not only with the quantifiable performance objectives but also with attitudes, behaviours and cultural issues. Therefore it is imperative that both 'hard' data and 'soft' issues are measured. Measurement will therefore include data from the audit of the pilot phase and the opinions, reflections and experiences of those involved in the change process. Once the change is agreed and implemented, it is necessary to reinforce it through education and training, appraisal, career development and reward systems (Senior & Swailes 2010).

3.8 Conclusion

While the team had varying opinions on this change project, all were willing to proceed with the pilot and any resistance to the planned change was based on the strongly held belief by some that it would not affect an improvement in patient safety.

4. Evaluation

'Evaluation is making a comparative assessment of the value of the evaluated or intervention, using systematically collected and analysed data, in order to decide how to act' (Øvretveit, J. 1998, pp.9).

4.1 Introduction:

The first recommendation in the Institute of Medicine's (IOM, 2001) report *Crossing the Quality Chasm* was that health care should be safe, timely, effective, efficient, equitable and patient centred. In order to achieve this, healthcare organisations must continually improve the services they provide. Increasingly there is demand and pressure to strive towards improvement and accountability. This has led to regulatory bodies, health insurers and patients looking for standardised quality measures such as patient satisfaction, hospital readmission rates and other healthcare outcomes (Solberg, 1997). However evaluating efforts to improve quality is complex and challenging (The Health Foundation, 2011). Parry et al (2013) recommend that the guiding question for those undertaking evaluation of health care improvement should be 'How and in what context does the new model work or can be amended to work?'

This chapter begins with a discussion on the importance of healthcare evaluation and an overview of four common evaluation models. It provides details of the methods of evaluation employed and the analysis carried out. The evaluation is directly linked with the objectives outlined for this development project.

4.2 The Importance of healthcare evaluation

Green & South (2006) state that healthcare should be evaluated in order to:

- Establish whether or not interventions have worked.
- Improve health programme implementation
- Provide accountability to funders
- Increase support for sustaining or expanding an intervention
- Contribute to the scientific base for interventions
- Impact policy decisions

Three drivers for measurement have been identified; measurement for improvement, accountability and research. (Solberg, 1997) The importance of measurement in the

improvement process is threefold. First it is necessary to identify those processes that need improvement. Then it is necessary to measure the particular process in question.

Thirdly it is important to re-measure in order to ascertain if the intervention has been effective in improving a process (Solberg, 1997). Measurement for accountability involves collection of data on outcomes or results and is intended to reveal and compare performance either at an institutional level or at an individual level. Measurement for research places huge importance on verifying that measures and data systems are precise, reliable and valid as the results of research measurement will most likely be generalised to a specialised group (Solberg, 1997)

The four most common health evaluations are experimental, economic, developmental and managerial. Each of these perspectives involves a set of assumptions about what is to be evaluated, what constitutes valid knowledge and the best way to measure this knowledge. (Øvretveit, J. 1998). Appropriately selected evaluation models allow academic managers to structure evaluation that accommodates a programmes true complexity (Frye & Hemmer, 2012).

4.3 Models of Evaluation

Three models of evaluation are reviewed, Kirkpatrick's approach; the Logic Model; and the Context/ Input/Process/Product (CIPP) model.

4.3.1 Kirkpatrick's four-level evaluation model

Kirkpatrick's four-level approach is popular as a model for evaluating learner outcomes in training programs. Its main contributions to educational evaluation are its focus on outcomes and its clear account of outcomes beyond simple learner satisfaction. Kirkpatrick suggested gathering data to assess four hierarchical "levels" of programme outcomes: (1) learner satisfaction or reaction to the programme; (2) measures of learning attributed to the programme; (3) changes in learner behaviour ; and (4) the programme's final results in its larger context (Kirkpatrick, D. 1996).

Kirkpatrick's model has been criticized for not taking intervening variables that affect learning into account and for its assumption of causation between the educational

programme and its outcomes (Frye & Hemmer, 2012). This model was not chosen as it is primarily focused on evaluation of education.

4.3.2 The logic model

Though often used during programme planning as well as an evaluation approach, the Logic Model structure strongly supports a coherent evaluation plan. The four basic components of the Logic Model are inputs, activities, outputs and outcomes (Frye & Hemmer, 2012). This model necessitates planners to clearly define the intended links between the programme resources (Inputs), their strategies or treatments (Activities), the immediate results of activities (Outputs), and the desired accomplishments (Outcomes).

The Logic Model can ensure that a programme, once implemented, actually focuses on the intended outcomes (Frye & Hemmer, 2012). Critics of this model argue that its inherent linearity can result in evaluators concentrating blindly on following the Model during programme implementation without looking for unexpected outcomes or flexibly facilitating mid-stream changes (Patton 2011). The linear nature of this model and its inability to generate evidence for causal associations between activities and outcomes (Frye & Hemmer, 2012) led the writer to discount it as a suitable model of evaluation for this project.

4.3.3 The CIPP (context/input/process/product) model.

The CIPP (context/input/process/product) model was first presented in 1971 and addresses all phases of an improvement programme: its context, inputs, process and product (Stufflebeam & Shinkfield 2007). The efficacy of the CIPP model across educational and non-educational evaluation settings has been comprehensively documented (Frye & Hemmer, 2012). The Context study findings provide a useful baseline for evaluating later outcomes. An Input evaluation can help to assess current practices against other potential practices. Its focus on feasibility and effectiveness allows a developing project to remain sensitive to the practices most likely to work well (Frye & Hemmer, 2012). The Process evaluation study is normally used to assess a projects implementation. This study also prepares the evaluator to interpret the programme's outcomes. The Product evaluation study aims to identify and assess outcomes, including both positive and negative outcomes, intended and unintended outcomes (Frye &

Hemmer, 2012). The writer believes that this model best suits evaluation of this improvement project and is a good fit with the Senior & Swailes organisational development model for change (see Figure. 3).

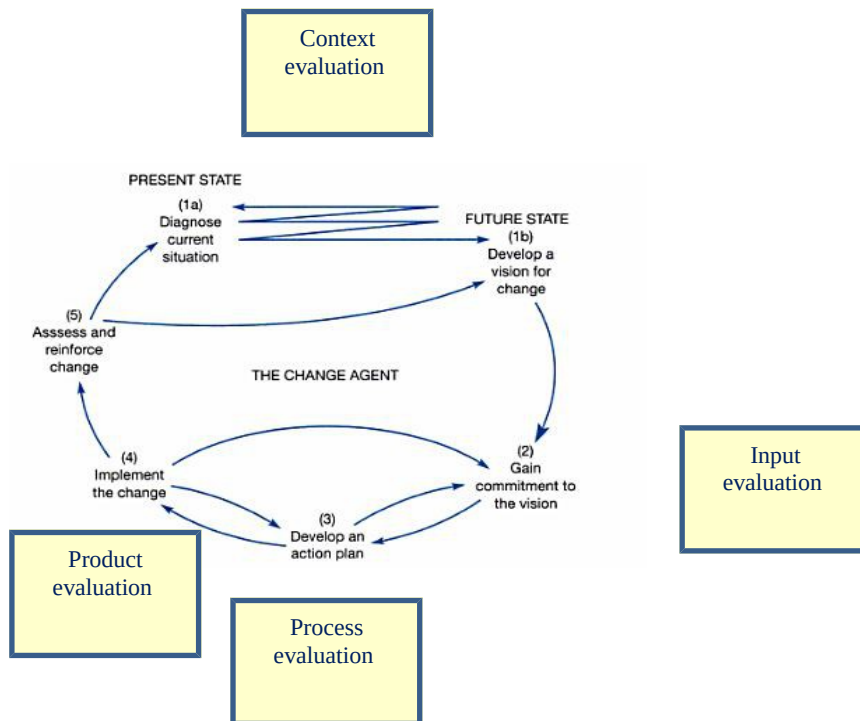


Figure 4: Senior & Swailes OD Model with CIPP evaluation studies

4.3.4 Methods and measures

Parry et al (2013) identify the need for evaluation methods to provide an understanding of why an improvement initiative does or does not work.

Throughout this Organisational Development project, both quantitative and qualitative designs were used. A quantitative approach has an objective reality independent of the subjects being studied (Yilmaz, 2013). This methodology was employed to ascertain the organisations present state, 'Time Out' practices in other private hospitals and the audit of the present and changed practice during pilot. A qualitative approach is subjective, reality or knowledge are socially constructed and the relationship between the knower and the known are inextricably linked (Yilmaz, 2013). This methodology was used before and after the change project and involved informal interviews with surgeons and staff. These interviews were a source of rich data and allowed the writer to collect information on a

range of possible subjects, including those which might become cause for resistance (Cummings & Worley, 2009).

4.3.4.1 Context evaluation.

A number of data collection and analysis methods lend themselves to a context study, including document reviews, interviews, focus groups and surveys (Frye & Hemmer, 2012). For the purposes of this evaluation, policy review, audit, survey and interviews were conducted in accordance with the objectives outlined for this project.

Objective 1: To complete a stakeholder analysis and agree an implementation team

One of the most important tasks during strategic change is the management of the interface between the many competing demands of an organization's stakeholders (Ackermann, 2011). The identification of the stakeholders for this change project was of vital importance and the analysis was conducted with the assistance of the theatre manager (Appendix 2). This analysis identified the following as having high power and interest: Consultant surgeons, theatre manager, hospital CEO, Quality manager, Theatre User Group and the Medical Director. Theatre staff were seen as having high interest but lower power. Anaesthetists were judged to have high power but lower interest. This determination identified the key players and who best to focus efforts. This analysis also strongly influenced the membership of the implementation team and it was decided that powerful stakeholders required representation on the team.

Objective 2: To conduct an observation audit of 'Time Out' practices to identify (diagnose) the current situation.

The purpose of this audit was to act as a baseline, assess present practices and identify opportunities to improve. An audit tool was constructed in accordance with the organisations *Protocol to ensure correct site, side, procedure, correct patient surgery (PP- Org-27)*. The tool identified the requirements for the verification and 'Time Out' process, documentation in the patient record and evidence of competency training of staff. With the agreement and assistance of the theatre manager and the verbal consent of the patients involved, the writer audited the verification and 'Time Out' process on four patients, one undergoing surgery in each of the organisations four theatres. The audit consisted of

direct observations from the first contact with the anaesthetic nurse in the theatre reception to the completion of the 'Time Out' process. The number audited was kept small for the following reasons:

- The purpose of the audit was not to improve compliance with hospital protocol but simply to confirm the 'present state'.
- This form of audit is time consuming
- The potential for bias due to the Hawthorn effect (Wickström & Bendix, 2000).
- Reluctance to conduct clandestine observation as it might diminish the collaborative nature of the change project.

Findings were documented and non-conformances and recommendations identified (Appendix 6). Findings in relation to the 'Time Out' process are displayed below.

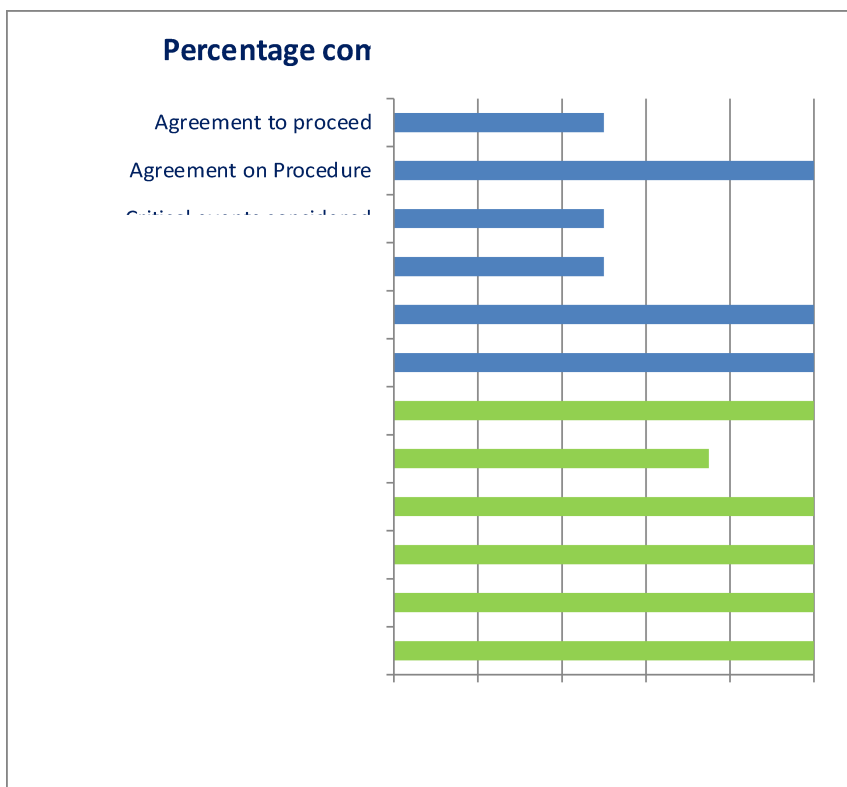


Figure 5 : Findings of Observational audit – Note - Criteria in Green relevant to change project.

Discussion:

In all four cases, 'Time Out' occurred before painting and draping, consent was checked and confirmed, patient identity was checked with the identity band and case notes, correct side/site was checked, there was agreement on the procedure and availability of implants

and images. Correct position was confirmed in three of the cases. In half the processes audited there was no discussion on concerns and critical events and no agreement to proceed verbalised although they are requirements of the policy. Incidentally it was noted that the policy directed verification to take place at the theatre reception between anaesthetics and ward nurses which meant that there was no formal input from the anaesthetist or the patient's consultant in the process.

Objective 3: Interviews with both surgeons and staff on the present state and their vision for the future.

Parry et al (2013) argue that every evaluation of improvement should start with clarity on the content and execution of the project and the degree of belief in it.

It was decided to conduct informal interviews with both surgeons and clinical nurse managers to identify their views and concerns and possible resistance to change. These interviews allowed themes to emerge and facilitated the construction of a mind map for the literature review (Appendix 7). The interviews were held informally in the theatre rest area and the interviewees were allowed to respond unrestrictedly so that new or unexpected views and experiences could emerge and be captured (Parry et al, 2013). In total seven Clinical Nurse Managers and fifteen surgeons were interviewed. The following themes were identified:

i) Confusion between patient verification and 'Time Out'

Some surgeons expressed the opinion that 'Time Out' should occur while the patient is awake and can confirm identity, procedure, site and side. There were discussions on the purpose of verification and the possibility that the patient, due to anxiety or co-morbidity could misidentify either themselves or the side/site for surgery as outlined in Abecassis (2015).

ii) Site marking

While those surgeons interviewed were happy to comply with the organisations protocol in regard to marking the surgical site and the use of the standard arrow, there was great variation among those interviewed on where the site mark should be placed. Some felt that placing it too close to the incision site compromised the surgical field or could end with

causing a tattooing effect. It was agreed that this would be investigated during the literature review.

iii) Timing of 'Time Out'

Both surgeons and nursing staff expressed the concern that moving directly to a change in practice might compromise the safety of patients and as such wanted any pilot to maintain the current 'Time Out' while adding a further 'Time Out' immediately prior to knife to skin. None of those interviewed were happy to proceed directly to a single 'Time Out' immediately prior to knife to skin.

iv) Operational issues

As nursing staff are the main drivers of 'Time Out' there was some concern that the second process would take time and cause delays in the surgical list and frustration from their medical colleagues. They also had concerns about contaminating the sterile field in an attempt to identify the patient under the drapes.

Discussion:

The interview process, while time consuming did have two main positive effects. The first was that it gave the writer a clearer view of what was required from the search of the literature. The second and more important result from this process was the level of engagement from both surgeons and staff. Opinions were canvassed and given openly, concerns were heard and discussed in an honest and frank manner and champions were identified and secured as members of the implementation team.

Objective 4: To conduct a survey of other private hospitals to ascertain practices in regard to 'Time Out'.

Senior and Swailes (2010) state organisations should gather data from within and about their external environment. Establishing the practices in regard to 'Time Out' in other hospitals was considered to be necessary and had been planned during stage 1 (a) of the project. However due to delays in Ethical approval and the concern that findings might influence the project, the survey, while conducted, did not take place until March and was limited to private hospitals.

The survey tool was constructed based on the National Policy and Procedure for Safe Surgery (Quality and Patient Safety Directorate, 2013) and drafted in consultation with the theatre manager and a number of surgeons. The tool consisted of fourteen closed questions concerning policy, checklist, those present during 'Time Out', who leads on the process, the timing of 'Time Out', patient positioning, patient identification, site marking and some background information on the respondents organisation (Appendix 8). The tool was piloted during a theatre educational open day in the organisation in January 2016.

The population agreed was the private hospitals in Ireland who are members of the Private hospitals representative body. This population was selected as the writer is a member of a subcommittee of this group and could gain buy in for the completion of the survey. There are twenty members in this group, three of whom do not have a surgical department and as such were out ruled. Another hospital does not presently have a representative on the committee and so was also out ruled. The survey was therefore sent to sixteen hospitals. In advance of survey, information regarding the writer, the purpose of the survey and the intended tool was circulated to prospective respondents (Appendix 9.). This was followed up the following day with a link to a web-based survey provider and was the respondents were asked to complete the survey on line. In total eleven hospitals responded to the survey, yielding a response rate of 69%. The findings are outlined in Table 1/2 & Figures 6/7.

Survey Results	Yes	No
Does your Hospital have a policy/procedure for safe surgery?	100% (11)	0%
Has policy been developed in line with the National Policy and Procedure for Safe Surgery (2013)?	100% (11)	0%
Does your theatre department use a safe surgery checklist?	91% (10)	9%(1)

Table 1: Survey results – Policy checklist

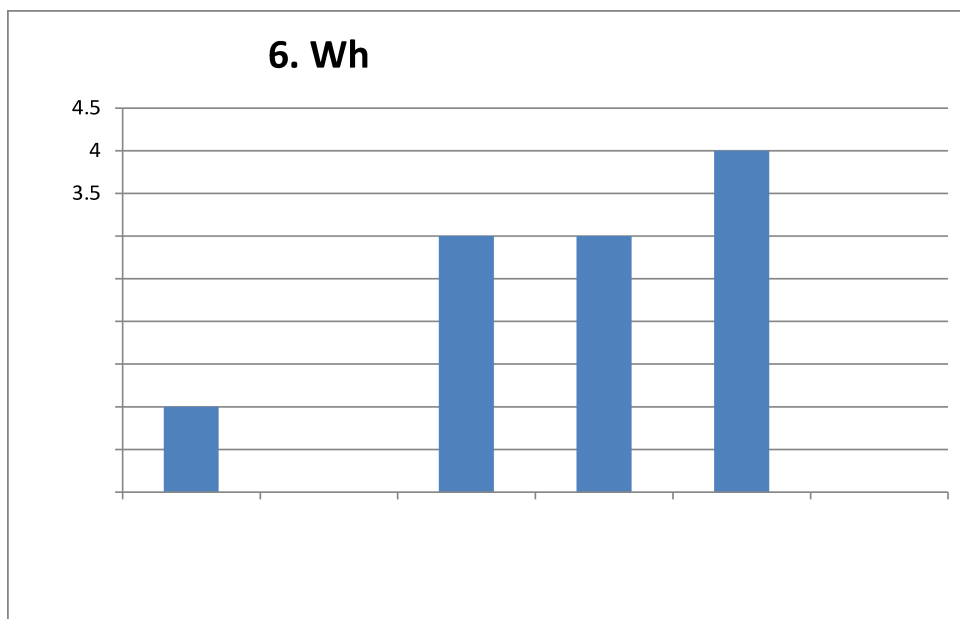


Figure 6 – Survey Results- Who leads on time out.

	Always	Usually	Sometimes
Is the consultant or operating surgeon who will be performing the skin incision present for timeout?	80% (8)	20% (2)	0%
Is the patient positioned before timeout is called?	30% (3)	40%(4)	30% (3)
Can the patient identity band be accessed during timeout?	82% (9)	0%	18% (2)
When necessary, is the surgical site mark visible during timeout	73% (8)	18% 2)	9% (1)

Table 2: Survey results – ‘Time out ‘criteria

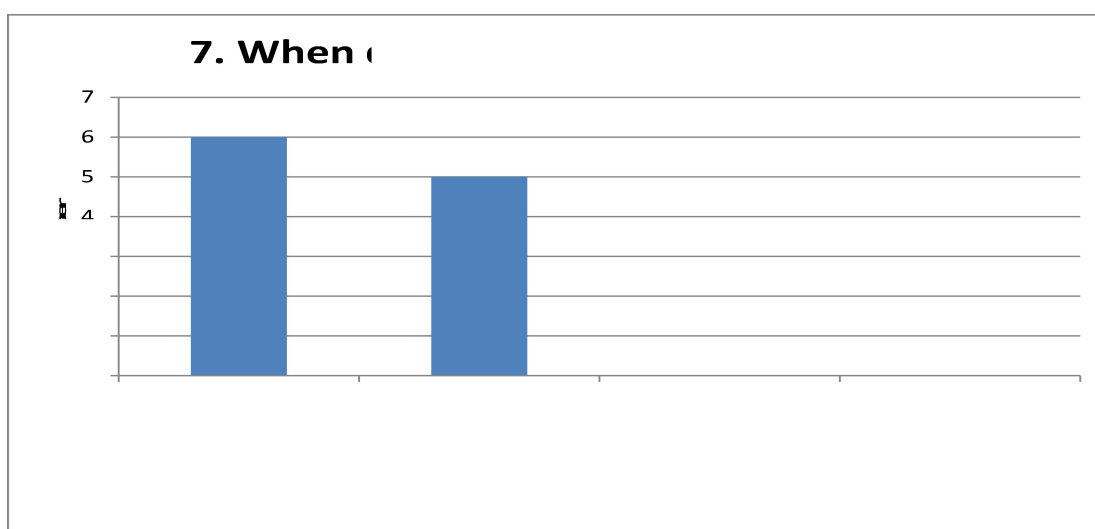


Figure 7: Survey results – Timing of ‘Time Out’

Discussion:

All hospitals surveyed had a policy in place which was developed in line with the national policy. Only one hospital did not use a checklist. 80% of respondents stated that the consultant was always present for time out. There was a large disparity when it came to the patient positioning and 82% could always access the ID band during time out. 9% of respondents stated that the site mark was sometimes visible during timeout. 55% of hospitals conduct 'Time Out' before painting and draping with 45% doing so before knife to skin.

These results show the wide diversity that exists in Ireland regarding 'Time out' practices and most of those organisations surveyed also possess JCI accredited status.

4.3.4.2 Input evaluation

Input evaluation asks, "How should it be done?" and identifies process designs and approaches that will most likely achieve the desired results (Zhang, et al, 2011). When applied to a process already in place, it can help assess current practice against other potential practices, focusing on feasibility and effectiveness (Frye & Hemmer, 2012).

Basic input evaluation measures include a proposed plan's relevance, feasibility, and advantage to other approaches, cost, and projected cost-effectiveness. Literature searches, use of advocate teams, and pilot trials are all suitable tools to identify and assess different project tactics (Zhang, et al, 2011).

The inputs required for this project were as follows:

- Stake holder analysis (Appendix 2)
- Review of literature, evaluation of which is outlined in Chapter 2
- Implementation team which included five surgeons, six clinical nurse managers, theatre manager and change agent.
- Agree audit tool for pilot

Cost implications of proposed change were minimal. Printing of audit tools was done internally. There was no anticipated loss of time or need to reduce the surgical list. The time spent by the implementation team in the planning and review of this project was given freely.

4.3.4.3 Process evaluation

Process evaluation monitors the project implementation process. It asks, “Is it being done?” and provides an ongoing check on the project’s progress. Important aims of this evaluation include recording the process and providing feedback regarding the extent to which the planned actions are carried out and whether changes or amendments of the plan are necessary (Zhang, et al, 2011). This study is invaluable for supporting accountability to the project stakeholders and allows for the data collection required for the projects continued improvement (Frye & Hemmer, 2012).

The pilot began on February 1st 2016 and was confined to those surgeons identified during the planning process and to procedures involving laterality, multiple structures and multiple levels. The theatre manager took a strong lead during the pilot phase, liaising with clinical nurse managers to ensure that the second ‘Time Out’ was conducted as agreed. Audit tools were available in each of the theatres and completed for the agreed consultants lists. Evaluation:

- All eight of the consultants identified during the planning phase participated in the pilot.
- 100% of the surgeries which fitted the criteria were audited. The breakdown of cases by specialty is displayed in the graph below.

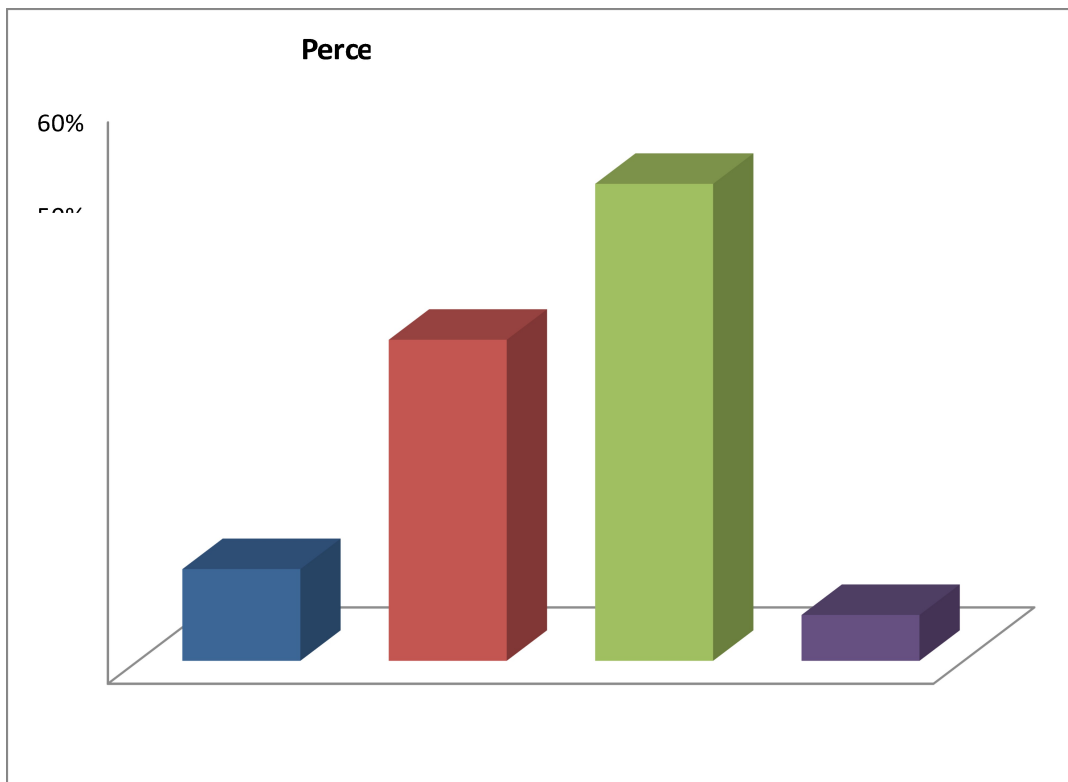


Figure 8: Percentage of Surgeries by Speciality

- 40% of Surgeons and 59% of anaesthetists conducted a secondary verification with the patient before the administration of anaesthesia.

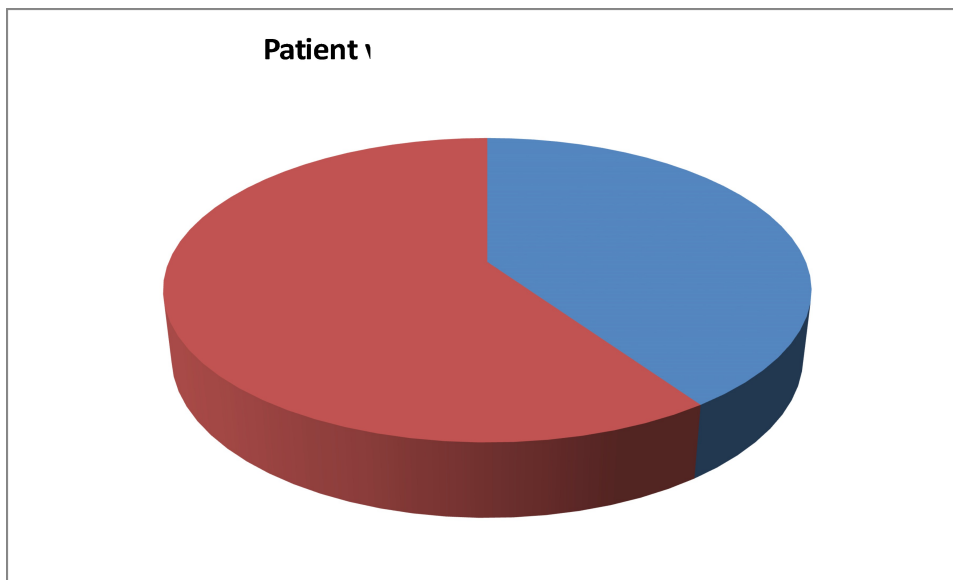


Figure 9: Patient verification by Consultants

- A second 'Time Out' was performed in 100% of the surgeries meeting the criteria of the pilot.

Discussion:

Whilst the suggestion to pilot a second verification process came from one of the surgeons, compliance among surgeons and anaesthetists was 40% and 60% respectively. Some of the consultants felt that they had only recently met with the patient and did not see the value of the secondary verification. The surgeon was not always available when the patient arrived in the theatre, sometimes having to go to consent another patient. Anaesthetists had a higher rate of participation and including them in the verification process in the future is one of the recommendations of this report.

4.3.4.4 Product evaluation

The final evaluation in the CIPP model is Product evaluation. This type of evaluation identifies and assesses the project outcomes including positive and negative outcomes (Frye & Hemmer, 2012). It asks, "Did the project succeed?" First, it provides cumulative information that can be used to judge the facts and effects of the project. Second, it provides formative information that can be used to make changes and improvement to the project for future implementation. Finally it offers insights on the project's sustainability and transferability (Zhang, et al, 2011). Stufflebeam and Shinkfield (2007) propose that a

combination of techniques should be used to assess outcomes. Doing so helps cross-check the different findings. Product evaluation of this project therefore includes review of the findings from the pilot and the feedback from the interviews held with those who participated in the pilot.

Findings:

Results of the pilot are displayed below. Four criteria were agreed for audit:

- i) Confirmation of patient identity
- ii) Confirmation of site mark
- iii) Confirmation of side of surgery
- iv) Confirmation of procedure

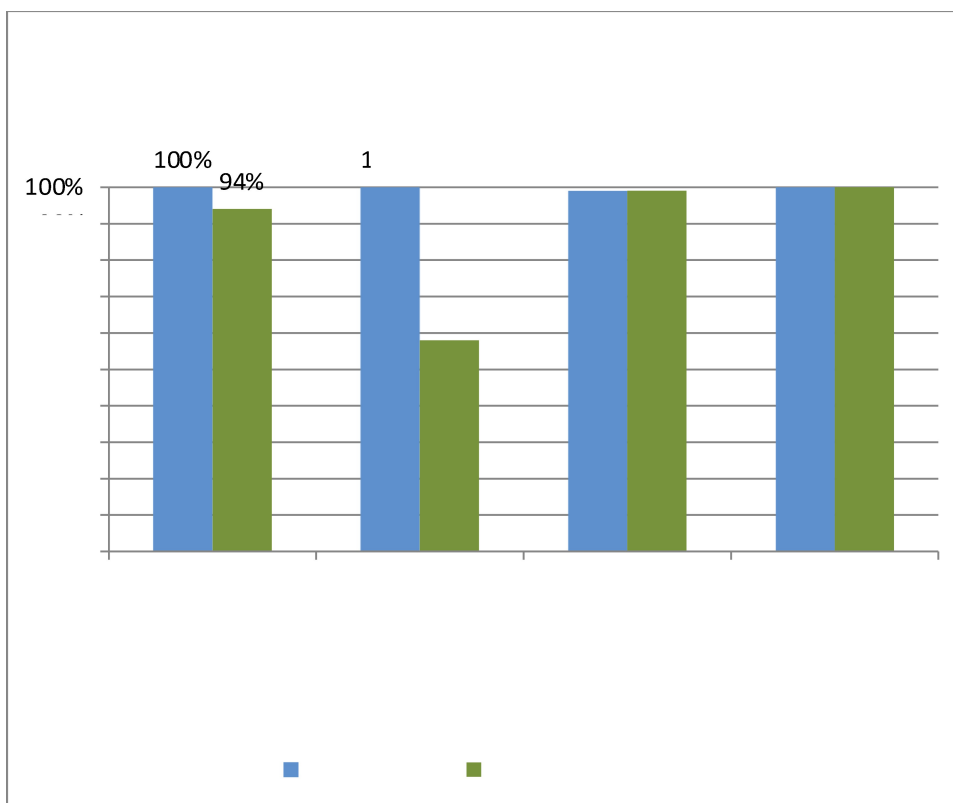


Figure 10: Pilot outcomes

Discussion:

Evaluation of outcomes is included under the criteria for audit and for ease of reporting will incorporate both the statistical findings and feedback from interviews.

Confirmation of patient identity: While the ability to identify the patient remained high at 94%, this statistic did not reflect inherent difficulties to reach that compliance level.

Subsequent interviews with staff highlighted significant difficulty in accessing the patients ID band once the patient was painted and draped and it became apparent during interview that some staff, in order to do their best to comply with the requirements, cut off the ID band to overcome these difficulties albeit that they knew this to be an inherently unsafe practice. Serious concern was expressed by staff about the fear of compromising the sterility of the surgical field.

Confirmation of site mark: The site mark was visible in only 58% of the secondary 'Time Out' processes. This is a significant drop and was due to two main reasons. The first cause of loss of visibility was the location of the site mark and its occlusion by the surgical drapes. The second cause was down to the removal of the mark during the painting process. Interviews with participating consultants and staff acknowledged that while there are opportunities to improve marking practices in the hospital, some surgeries (particularly in ophthalmic surgery) afford little opportunity to mark the side/site in an area which will remain visible once the patient is draped. There was also reluctance on behalf of some of the consultants to mark too close to the site of incision.

Confirmation of side of surgery: In only one case did staff report being unable to confirm side of surgery. This was due to the fact that the side was not documented on the patient consent form. During interview, staff clarified that their confirmation of side during the secondary 'time out' and in the absence of a visible site mark, was made solely on what was documented in the consent.

Confirmation of procedure: In all cases staff were able to confirm the procedure by referring to the consent form. However during interview, some staff expressed the concern that the theatre listing does not always match exactly what is documented in the individual patients consent form. This reflects what Paull et al (2015) refers to as 'upstream' margin for error relating to the Universal Protocol. This mismatch has serious potential for error as staff other than the nurse who performs the verification use this list when setting up the theatre and position equipment without reference to the consent form.

Final Comments:

The feedback from both staff and consultants was indeed rich and it was obvious that those involved were engaged and eager to do what was in the best interests of the patient.

The main points highlighted were as follows:

- Checking the patients identity once painted and draped was a big issue for the nursing staff, described by one nurse as a “nightmare” for the reasons outlined above. This was particularly relevant in some orthopaedic cases.
- Once painting and draping commences, staff are busy, plugging in diathermy, picking items, arranging drapes etc. and could easily be distracted.
- Painting and draping is seen as the start of the procedure, patient is in position and “once the surgeon paints & drapes, it is a challenge to get them to stop”.
- Some staff and consultants felt that once the patient is draped, they lose the anatomical context of the patient, they “cannot see the landmarks” and this they believe increases the risk to the patient.
- Although the writer could find no evidence of a linkage between site marking and tattooing, some surgeons stated that they have experience of patients questioning the “blue mark” at follow up.
- The overwhelming conclusion from all involved and the decision of the implementation team is that this change should not be implemented at present but the team have made recommendations which will be outlined in Chapter 5.

5. Discussion & Conclusions

"There is nothing wrong with change, if it is in the right direction". - Winston Churchill (1874-1965)

Introduction

This OD project, on the face of it was a simple matter of moving a process forward by a number of minutes. At the outset it appeared to some that it barely warranted a full Organisational Development project. However, the writer knew that the organisations current practice had not evolved by accident but because it was perceived to be the safest way to do 'Time Out'.

This chapter draws together the findings of this project, how the programme was shaped by the review of literature and the writers experience of introducing this change project. The writer will also analyse the impact of this project on the organisation, the opportunities for improvement identified and the contribution it can make to practice and possibly theory. In conclusion, while this project did not achieve its stated aim and was not implemented, where the organisation goes from here and how we affect change which will strengthen our patient safety systems will be the measure of our success.

5.1. First do no harm

Despite the relatively infrequent occurrence of wrong site surgery it continues to happen and it is one of the events that both surgeons and theatre staff fear the most. Notwithstanding all of the interventions from the Joint Commission, the World Health Organisation and many others, one hundred and eleven events were reported to the Joint Commission in 2015 (Appendix 3) and sixty three wrong site surgeries have been reported in Irish hospitals since 2011(Irish Times, 2016). The literature is rich with information on 'never events' and what root causes of these incidents have been identified (Abecassis, 2015; Blanco *et al.*, 2009; Michaels *et al.*, 2007; Stahel, 2014). It makes for stark reading particularly as the results resonate with our own experiences and are mirrored in some the evaluations during this change project. Blanco *et al.*, (2009) finding that in 56% of occurrences the surgical site was not visible during 'Time Out' is concerning as the site mark was not visible in 42% of cases after painting and draping during this project.

5.2 Where theory meets practice

At the start of this project time was spent in ascertaining current practice and discussing with key stakeholders the vision for change. Through collaboration and honest discussion a plan was decided and a vision for change agreed. The vision was that the organisation will never have a never event and it was hoped that this change would decrease the likelihood of that happening. There were concerns however and through the interview process surgeons and staff were encouraged to outline their fears so that they could be researched in the literature and hopefully allayed. This is also why the dual system was agreed, the change agent could not ethically or morally suggest that individuals change their practice to what was perceived to be a less safe one. The following paragraphs summarise some of the key findings.

Site Marking

Visibility of the site mark was one of the areas highlighted by both surgeons and nursing staff as being a huge concern in the changed process and indeed is well documented in the literature. While some consultants did agree that there was opportunity to improve their practices and one surgeon changed his practices during the pilot, the consensus was that 'time out' should occur when the site mark is visible and that is before painting and draping. Cobb (2012) argues that a mark washed of by surgical prep may pose more of a threat to the patient.

Patient identity

While reduction in the ability to identify the patient only dropped by 6%, there was no doubt in the subsequent interviews that this posed a serious challenge for nursing staff. In the survey of hospitals, 82% of respondents indicated that they could always identify the patient during time out, Vats *et al.*, (2010) suggest conducting time out prior to draping because otherwise name bands cannot be accessed without compromising sterility.

Confirmation of Procedure

During this change project it was noted that the reporting of near misses (locally called Good Catches) increased substantially as staff, with heightened awareness noted lack of

laterality on theatre list details or on consent forms. This is described by Paull *et al.*, (2015) as upstream and downstream errors which can occur weeks before the patient reaches the hospital.

Loss of anatomical context

Loss of visibility of the patient's position once draped is challenging and can cause confusion regarding laterality. Seiden (2006) argues that when the patient is covered with drapes, it necessitates serious mental effort for the surgeon to determine right from left. This has been found to be particularly challenging for orthopaedic and spinal surgery. In interviews following the change pilot, both surgeons and nursing staff referred to the draping as losing sight of the landmarks.

Organisational impact

This OD project has had a positive impact on the organisation and particularly on the staff who participated. Awareness of the issues surrounding never events and patient safety in theatre has been greatly heightened and anecdotally staff are reporting that already some practices in regard to site marking and verification of patients have changed. Reporting of good catches has increased three fold and theatre staff are highlighting poor scheduling information to consultant secretaries.

Contribution to practice/theory

It is hoped that the findings of this project can be published and start a debate about the timing of 'Time Out'. 55% of the hospitals surveyed conduct time out before painting and draping and the national policy allows for this practice to be adapted locally. Concerns are to be found in the literature and a review of the articles references by the WHO in their guiding document did not yield any success on a secure evidence base for their mandate that the process occur prior to knife to skin.

5.3 Strengths of this project

While the project did not achieve its aim to have 'time out' conducted immediately prior to knife to skin in 100% of surgeries, this does not mean that the change project is at an end. A number of opportunities for improvement have been identified and will be outlined in recommendations for future improvements .

5.4 Limitations

The main limitation to this study is that the writer was not in a position to conduct the survey in public hospitals. To have survey data from the public system would add considerably to the knowledge of where Irish hospitals are in relation to 'Time out' practices.

5.5 Ethical considerations

The writer received ethical approval to conduct the survey from her organisations Clinical Ethics Committee.

5.6 Recommendations for future improvements

Following a meeting of the implementation team and a review of Joint Commission targeted solutions the following are recommendations for further improvements:

- 1) Review scheduling practices and the possibility of cross referencing the surgeon's notes with the consent form and theatre lists.
- 2) Review verification process to formally involve the anaesthetist in the process.
- 3) Review site marking practices with surgeons so that where possible the site is visible after painting and draping.
- 4) Review markers used for site marking
- 5) Review organisational policy and amend to reflect any changes agreed.
- 6) Look at opportunities to improve practice by examining what is going right as well as what happens when something goes wrong.

This is not the end but rather the beginning. It is now down to the organisation and all those involved to take the learning from this change project and progress it into something meaningful and potentially transformational.

References

- Abecassis, Z.A., McElroy, L.M., Patel, R.M., Khorzad, R., Carroll, C. & Mehrotra, S. (2015). Applying fault tree analysis to the prevention of wrong-site surgery [Electronic version]. *Journal of Surgical Research*, 193(1), 88-94.
- Agency for Healthcare Research and Quality (AHRQ), Patient Safety Network. Retrieved from psnet.ahrq.gov/primers/primer/3/never-events
- Ahmad Uraiqat, M.D., Rubeihat, H., Alsudi, M., & Amer Amireh, M.D. (2015). Surgeons' Learning Style in Comparison to their Medical Colleagues [Electronic version]. *Journal of the Royal Medical Services*, 22(4), 24.
- Authority, Pennsylvania Patient Safety (2008). Doing the right things to correct wrong-site surgery [Electronic version]. *Patient Safety Advisory*, 4(2), 29-45.
- Barnard, M. & Stoll, N. (2010). Policy report Organisational Change Management: A rapid literature review, *University of Bristol* [Electronic version]. Number 10/01.
- Batras, D., Duff, C., Smith, B.J. (2014). Organizational change theory: implications for health promotion practice. *Health promotion international*, 31(1), 231-241.
- Blanco, M., Clarke, J.R., Martindell, D. (2009). Wrong site surgery near misses and actual occurrences. *AORN journal*, 90(2), 215-222.
- Bloomfield, A.L. (2004). (attributed). Quoted in: Cuervo, L.G. The road to healthcare [Electronic version]. *British Medical Journal*, 329(7456), 1-2.
- Bosk, C.L., Dixon-Woods, M., Goeschel, C.A., & Pronovost, P.J. (2009). Reality check for checklists. *The Lancet*, 374(9688), 444-445.
- Bullock, R.J. & Batten, D. (1985). It's just a phase we're going through: a review and synthesis of OD phase analysis [Electronic version]. *Group & Organization Management*, 10(4), 383-412.
- Burnes, B. (2004). Kurt Lewin and the planned approach to change: a re-appraisal. *Journal of Management Studies*, 41, 977-1002.
- Catchpole, K., & Russ, S. (2015). The problem with checklists [Electronic version]. *BMJ Quality & Safety*, 24, 545-549.
- Clarke, J. R. (2014). Is your office helping you prevent wrong site surgery? [Electronic version]. *Bulletin of the American College of Surgeons*, 99(4), 28-31.
- Clarke, J. R. (2015). Wrong surgery: why does not the Universal Protocol solve the problem? [Electronic version] *The American Journal of Surgery*, 210(1), 14.
- Cobb, T. K. (2012). Wrong site surgery—where are we and what is the next step? [Electronic version]. *Hand*, 7(2), 229-232.

Coghlan, D., & Brannick, T. (2014). *Doing action research in your own organization*. London: Sage Publications.

Conrardy, J. A., Brenek, B. & Myers, S. (2010). Determining the state of knowledge for implementing the universal protocol recommendations: an integrative review of the literature [Electronic version]. *AORN journal*, 92(2), 194-207.

Cummings, T. & Worley, C. (2014). *Organization development and change*. California: Cengage learning.

DeVine, J., Chutkan, N., Norvell, D.C., & Dettori, J.R. (2010). Avoiding wrong site surgery: a systematic review [Electronic version]. *Spine*, 35(9S), S28-S36.

Donabedian, A. (1988). The Quality of Care – How can it be assessed? [Electronic version]. *The Journal of the American Medical Association*, 260(12), 1743- 1748. for Safe Surgery (2013). *Patient Safety First*. Retrieved from: hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/SafeSurgery/

French, R. (2011). *Organizational behaviour*. Oxford: John Wiley & Sons.

French, W. L. & Bell, C.H. (1999). *Organizational Development: Behaviour Science Interviews for Organization Improvement*. New Jersey: Prentice Hall.

Frye, A.W., & Hemmer, P.A. (2012). Program evaluation models and related theories: AMEE guide no. 67 [Electronic version] *Medical Teacher*, 34(5), 288-299.

Green, J. & South, J. (2006). *Evaluation*. Maidenhead: Open University Press/McGraw-Hill Education.

Hadjipavlou, A.G., & Marshall, R.W. (2013). Wrong site surgery: the maze of potential errors [Electronic version].. *Bone & Joint Journal*, 95(4), 434-435.

Hanchanale, V., Rao, A.R., Motiwala, H., & Karim, O.M.A. (2014). Wrong site surgery! How can we stop it? [Electronic version]. *Urology Annals*, 6(1), 57–62. *Harvard Business Review*, 1-11

Haynes, A.B., Weiser, T.G., Berry, W.R., Lipsitz, S.R., Breizat, A H.S., Dellinger, E.P. & Merry, A.F. (2009). A surgical safety checklist to reduce morbidity and mortality in a global population [Electronic version]. *New England Journal of Medicine*, 360(5), 491-499.

Health Service Executive (2008). *Improving Our Services: A Users' Guide to Managing Change in the Health Service Executive*.

Hempel, S., Maggard-Gibbons, M., Nguyen, D.K., Dawes, A.J., Miake-Lye, I., Beroes, J.M. & Shekelle, P.G. (2015). Wrong-site surgery, retained surgical items, and surgical fires: a systematic review of surgical never events [Electronic version]. *JAMA surgery*, 150(8), 796-805.

Hollnagel, E., Wears, R.L., Braithwaite, J. (2015). From Safety-I to Safety-II: A White Paper. *Resilient Health Care Net*.

Institute of Medicine (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington DC: National Academy Press.

Isaksson, R., Hallencreutz, J., Turner, D.M. & Garvare, R. (2011). *Change Management from a Stakeholder Perspective*. Paper presented at the QMOD Conference, San Sebastian, Spain.

Joint Commission (2015). *Sentinel event data: event type by year*.
http://www.jointcommission.org/se_data_event_type_by_year_/ Sentinel Event Statistics Data - Event Type by Year (1995 - 2015).

Joint Commission International (2014). *Accreditation Standards for Hospitals* (5th edn). Illinois: Joint Commission International.

Joint Commission on Accreditation of Healthcare Organization (2004). *Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery*. Retrieved from jointcommission.org/PatientSafety/UniversalProtocol/.

Kim, F.J., daSilva, R.D., Gustafson, D., Nogueira, L., Harlin, T. & Paul, D. L. (2015). Current issues in patient safety in surgery: a review [Electronic version]. *Patient Safety in Surgery*, 9(1), 1-9.

Kirkpatrick, D. (1996). Revisiting Kirkpatrick's four-level model [Electronic version]. *Training & Development*, 50(1), 54-57.

Kotter, J. P., & Schlesinger, L. A. (1979). Choosing strategies for change.

Kotter, J.P. (1996). *Leading Change*. Boston: Harvard Business School Press.

Kübler-Ross, E. (1973). *Coping with Death and Dying*. Ziff-Davis New York, NY

Lee, S.H., Kim, J.S., Jeong, Y.C., Kwak, D.K., Chun, J.H. & Lee, H.M. (2013). Patient safety in spine surgery: regarding the wrong-site surgery [Electronic version].. *Asian Spine Journal*, 7(1), 63-71.

Lewin, K. (1947). Frontiers in group dynamics II. Channels of group life: Social planning and action research [Electronic version].. *Human Relations*, 1(2), 143-153.

Lingard, L., Regehr, G., Orser, B., Reznick, R., Baker, G. R., Doran, D. & Whyte, S. (2008). Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication [Electronic version]. *Archives of Surgery*, 143(1), 12-17.

- Logan, C.A., Cressey, B.D., Wu, R.Y., Janicki, A.J., Chen, C.X., Bolourchi, M.L. & Fairchild, D.G. (2012). Monitoring universal protocol compliance through real-time clandestine observation by medical students results in performance improvement [Electronic version]. *Journal of Surgical Education*, 69(1), 41-46.
- Maes, G., & Van Hootegeem, G. (2011). Toward a dynamic description of the attributes of organizational change [Electronic version]. *Research in Organizational Change and Development*, 19, 191-231.
- Mahar, P., Wasiak, J., Batty, L., Fowler, S., Cleland, H. & Gruen, R.L. (2012). Interventions for reducing wrong-site surgery and invasive procedures (review) [Electronic version] *Cochrane Collaboration*, 9, 1-43.
- Masud, D., Moore, A. & Massouh, F. (2010). Current practice on preoperative correct site surgical marking [Electronic version]. *The Journal of Perioperative Practice*, 20(6), 210.
- McAuliffe, E., & Van Vaerenbergh, C. (2006). *Guiding change in the Irish health system*. Dublin: HSE Organisation Development and Design.
- Michaels, R.K., Makary, M.A., Dahab, Y., Frassica, F.J., Heitmiller, E., Rowen, L.C. & Pronovost, P.J. (2007). Achieving the National Quality Forum's "Never Events": prevention of wrong site, wrong procedure, and wrong patient operations [Electronic version]. *Annals of Surgery*, 245(4), 526-532.
- Moppett I.K. & Moppett SH, (2016). The risk of surgical never events [Electronic version]. *British Journal of Hospital Medicine*, 77(2), 64.
- Neily, J., Mills, P.D., Eldridge, N., Carney, B.T., Pfeffer, D., Turner, J.R. & Bagian, J.P. (2011). Incorrect surgical procedures within and outside of the operating room: a follow-up report [Electronic version]. *Archives of Surgery*, 146(11), 1235-1239.
- NHS (2013) *Institute for Innovation and Improvement 2006-2013 – Stakeholder Analysis*. Retrieved from institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/stakeholder_analysis.html
- Nillson, L., Lindberget, O., Gupta, A & Vegfors, M. (2010). Implementing a pre-operative checklist to increase patient safety: a 1-year follow-up of personnel attitudes [Electronic version]. *Acta Anaesthesiologica Scandanavica*, 54(2), 176-182.
- O'Connor, P., Reddin, C., O'Sullivan, M., O'Duffy, F., & Keogh, I. (2013). Surgical checklists: the human factor [Electronic version]. *Patient safety in surgery*, 7(1), 1.
- O'Connor, P., Ryan, S., & Keogh, I. (2012). A comparison of the teamwork attitudes and knowledge of Irish surgeons and US Naval aviators [Electronic version]. *The Surgeon*, 10(5), 278-282.

Øvretveit, J. (1998). Evaluating health interventions: an introduction to evaluation of health treatments, services, policies and organizational interventions. Berkshire: Open University Press.

Parry, G.J., Carson-Stevens, A., Luff, D.F., McPherson M.E. & Goldmann, D.A. (2013). Recommendations for evaluation of healthcare improvement initiatives. [Electronic version] *Academic Paediatrics*, 23(6s), 24-29.

Patton, M.Q. (2011). Developmental evaluation: Applying complexity concepts to enhance innovation and use. New York: Guilford Press.

Paull, D.E., Mazzia, L.M., Neily, J., Mills, P.D., Turner, J.R., Gunnar, W. & Hemphill, R. (2015). Errors upstream and downstream to the Universal Protocol associated with wrong surgery events in the Veterans Health Administration [Electronic version]. *The American Journal of Surgery*, 210(1), 6-13.

Pickering, S.P., Robertson, E.R., Griffin, D., Hadi, M., Morgan, L.J., Catchpole, K.C. & McCulloch, P. (2013). Compliance and use of the World Health Organization checklist in UK operating theatres [Electronic version]. *British Journal of Surgery*, 100(12), 1664-1670.

Pikkel, D., Sharabi-Nov, A. & Pikkel, J. (2014). The importance of side marking in preventing surgical site errors [Electronic version]. *International Journal of Risk & Safety in Medicine*, 26(3), 133-138.

Pugh, D. (1993). Understanding and managing organizational change. *Managing change*, 2, 108-112.

Quality and Patient Safety Directorate, National Policy and Procedure for Safe Surgery (2013). Retrieved from:
http://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/Safe_Surgery/

Ragusa, P.S., Bitterman, A., Auerbach, B. & Healy III, W.A. (2016). Effectiveness of Surgical Safety Checklists in Improving Patient Safety [Electronic version]. *Orthopedics*. 39(2) 307-310. Electronic version

Reason, J.T. (1990). *Human error*. New York: Cambridge University Press.

Russ, S. J., Sevdalis, N., Moorthy, K., Mayer, E. K., Rout, S., Caris, J. & Darzi, A. (2015). A qualitative evaluation of the barriers and facilitators toward implementation of the WHO surgical safety checklist across hospitals in England: lessons from the "Surgical Checklist Implementation Project" [Electronic version]. *Annals of surgery*, 261(1), 81-91.

Rydenfält, C., Johansson, G., Odenrick, P., Åkerman, K., & Larsson, P. A. (2013). Compliance with the WHO Surgical Safety Checklist: deviations and possible improvements [Electronic version]. *International Journal for Quality in Health Care*, 25(2), 182-187.

- Schein, E.H. (1996). 'Kurt Lewin's change theory in the field and in the classroom: notes towards a model of management learning' [Electronic version]. *Systems Practice*, 9(1), 27–47.
- Seiden, S.C., & Barach, P. (2006). Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: are they preventable? [Electronic version]. *Archives of surgery*, 141(9), 931-939.
- Senior, B. & Swailes, S. (2010) *Organisational change*. Edinburgh: Pearson Education.
- Sim, D.A., Feasey, N., Wren, S., Breathnach, A., & Thompson, G. (2009). Cross-infection risk of felt-tipped marker pens in cataract surgery [Electronic version]. *Eye*, 23(5), 1094-1097.
- Sim, F.C.J., Angadi, D., Jarvis, G. E., & Porteous, M. (2016). Assessing clarity and erasability of commercially available pens for surgical site marking: a comparative study in human volunteers [Electronic version]. *Patient Safety in Surgery*, 10(1), 1.
- Sirkin, H.L., Keenan, P. & Jackson, A. (2005). The hard side of change management [Electronic version]. *Harvard Business Review*, 83(10), 108.
- Smith, I. (2005). Continuing professional development and workplace learning 11: managing the 'people' side of organizational change [Electronic version]. *Library Management*, 26(3), 152-5.
- Solberg, L.I., Mosser, G. & McDonald, S. (1997). The three faces of performance measurement: improvement, accountability and research. *Joint Commission Journal of Quality Improvement*, 23(3), 135–147.
- Stahel, P.F. (2014). The tenth year of the “Universal Protocol”: are our patients safer today? *Bone and Joint* 360, 3(1), 7-10.
- Stufflebeam, D.L. & Shinkfield, A.J. (2007). Evaluation theory, models, and applications. *JAMA*, 299(22), 2690- 2696
- Thakkar, S.C. & Mears, S. C. (2012). Visibility of surgical site marking: A prospective randomized trial of two skin preparation solutions [Electronic version]. *The Journal of Bone & Joint Surgery*, 94(2), 97-102.
- The Health Foundation (2011). *Evaluating healthcare quality improvement A summary of learning from a Health Foundation roundtable*. June 2011
- Urbach, D.R., Govindarajan, A., Saskin, R., Wilton, A.S. & Baxter, N.N. (2014). Introduction of surgical safety checklists in Ontario, Canada [Electronic version]. *New England Journal of Medicine*, 370(11), 1029-1038.
- Wang, M. & Serak, J. (2014). “Time Out” For Surgical Safety Checklists? [Electronic version]. *Neurosurgery*, 75(2), 14-15.

Weiglein, G. (2011). The surgical safety checklist [Electronic version]. *Royal College of Surgeons in Ireland Student Medical Journal*, 4, 67-69.

Wickström, G. & Bendix, T. (2000). The "Hawthorne effect"—what did the original Hawthorne studies actually show?. [Electronic version]. *Scandinavian journal of work, environment & health*, 363-367.

World Health Organisation (WHO) (2009). *Guidelines for Safe Surgery: safe surgery saves lives*. Retrieved from who.int/patientsafety/safesurgery

Yilmaz, K. (2013). Comparison of Quantitative and Qualitative Research Traditions: epistemological, theoretical, and methodological differences [Electronic version]. *European Journal of Education*, 48(2), 311-325.

Zhang, G., Zeller, N., Griffith, R., Metcalf, D., Williams, J., Shea, C. & Misulis, K. (2011). Using the context, input, process, and product evaluation model (CIPP) as a comprehensive framework to guide the planning, implementation, and assessment of service-learning programs [Electronic version]. *Journal of Higher Education Outreach and Engagement*, 15(4), 57-84.

Zhao, X., Chen, J., Fang, X.Q., & Fan, S.W. (2009). Surgical site marking will not affect sterility of the surgical field [Electronic version]. *Medical Hypotheses*, 73(3), 319-320.

Bibliography

American College of Orthopaedic Surgeons (2015). *Guidelines on ensuring correct patient, correct site, and correct procedure surgery*. Retrieved from aaos.org/member/safety/guidelines.cfm

Association of PeriOperative Registered Nurses (2003). *AORN position statement on correct site surgery* [position statement]. Retrieved from: aorn.org/about/positions/correctsite.htm.

Baathe, F. & Erik Norbäck, L. (2013). Engaging physicians in organisational improvement work [Electronic version]. *Journal of health organization and management*, 27(4), 479-497.

Braithwaite, J., Wears, R. L., & Hollnagel, E. (2015). Resilient health care: turning patient safety on its head [Electronic version]. *International Journal for Quality in Health Care*, 27(5), 418-420.

Eden, C. & Ackermann, F. (1998). *Making Strategy: The Journey of Strategic Management*. London: Sage Publications.

Treadwell, J.R., Lucas, S., & Tsou, A.Y. (2013). Surgical checklists: a systematic review of impacts and implementation [Electronic version] *BMJ Quality & Safety*

Vas, A. & Lejeune, C. (2005). Revisiting Resistance to Change at the University: An Interpretative Approach. IAG School of Management, University of Leuven, Belgium.
20

Appendix 1

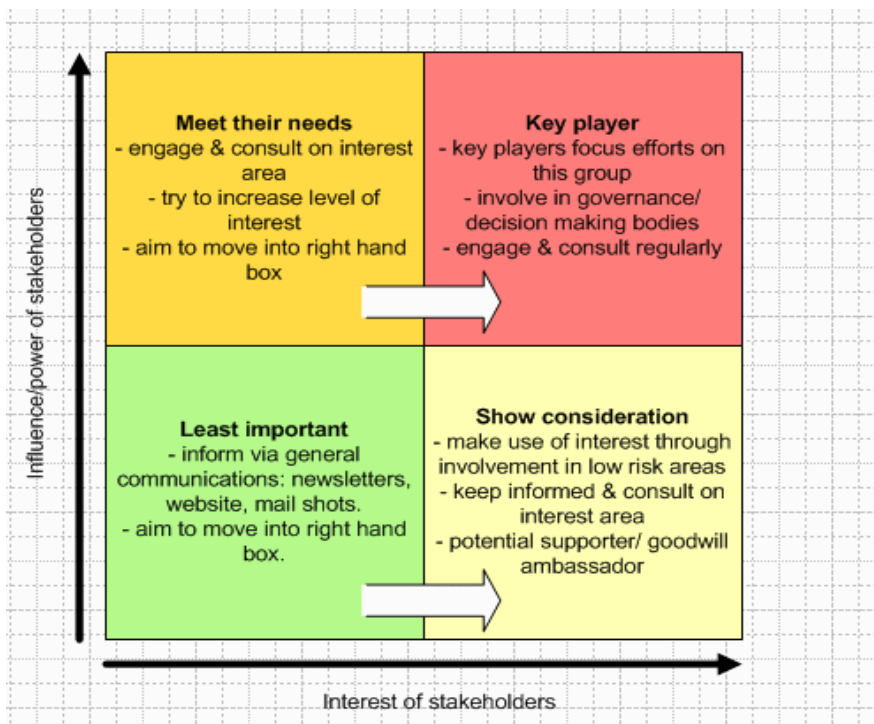
Project Plan

ID	Task Name	Start	Finish	Duration	2015					2016			
					Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
1	Complete a stakeholder analysis and agree implementation team	01/09/2015	30/10/2015	8w 4d									
2	Conduct an audit of 'Time out' practices	01/09/2015	30/10/2015	8w 4d									
3	Conduct interviews with surgeons/staff	01/10/2015	30/11/2015	8w 3d									
4	Complete literature review	01/10/2015	31/12/2015	13w 1d									
5	Conduct a survey of hospitals	01/01/2016	22/07/2016	29w 1d									
6	Implement change of practice on pilot basis	01/02/2016	02/03/2016	4w 3d									
7	Complete pilot and analyse data	14/03/2016	01/04/2016	3w									
8	Full implementation	01/04/2016	29/04/2016	4w 1d									

Appendix 2

Stakeholder Analysis

POWER	High		Consultant Surgeons Theatre Manager CEO/Management Quality/Safety Managers Theatre User Group Medical Director
	Low	Anaesthetists Patients Ward Staff	Theatre Staff
		Low	High
		INTEREST	



Appendix 3

Observation Audit Tool

Audit of verification and time out process in accordance with PP Org 27 – Section 2.2 – 3.5 Date: 28/09/15		
Requirements	Findings	Non Conformance/ Recommendation
<p>Verification</p> <p>Correct identification</p>	<p>Verification process reviewed at theatre reception for 2 of the 4 patients Refer. Doc BSHG 102 Rev. 11</p> <p>Patient: 1 – This verification was not observed so audit based on documentation. Identification ticked.</p> <p>Patient: 2 – Verification observed. Anaesthetic nurse asked patient to confirm name and date of birth and checked patient ID band.</p> <p>Patient: 3 - Verification observed. Anaesthetic nurse asked patient to confirm name and date of birth and checked patient ID band.</p> <p>Patient: 4 - This verification was not observed so audit based on documentation. Identification ticked.</p>	<p>Pin not included Verification conducted very well</p> <p>Very good handover of patient, very thorough Pin not included LMP –Pregnancy – indicated as N/a but patient within childbearing years – pregnancy test carried out</p> <p>Add reference to Patient identification policy</p>
Site marked- visual check	<p>Patient: 1 – Performed by consultant in the anaesthetic room, this is in accordance with policy PP ORG 27</p> <p>Patient: 2 – site mark not applicable in this case</p> <p>Patient: 3 – Site was visually checked at theatre reception</p> <p>Patient: 4 – Marked as checked –visually checked at reception</p>	<p>Nurse questioned had a very good knowledge of the process</p> <p>Nurse questioned knew process but vague on certain specifics of the process</p>
Consent	<p>Patient: 1 – Consent checked</p> <p>Patient: 2 – Consent checked</p> <p>Patient: 3 – Consent checked</p>	

	Patient: 4 – Consent checked	
Procedure	Patient: 1 – Procedure was confirmed Patient: 2 – Procedure confirmed Patient: 3 – Procedure confirmed Patient: 4 – Procedure confirmed	
Side and site	Patient: 1 – This was done in anaesthetic room with availability of ultrasound guidance Patient: 2 – Site only on confirmation checklist – verification section and no opportunity for N/A Patient: 3 – Confirmed with patient Patient: 4 – Confirmed with patient	Add side and Not applicable to site to BSHG 102 Rev. 11 A/A
Scrub nurse verifies Equipment	Patient: 1 – no evidence of same Patient: 2 – no evidence of same Patient: 3- no evidence of same Patient: 4 - no evidence of same	PP-ORG-27 states in 2.3 the circulating/scrub nurse will verify that any required medical technology and/or implants are available- no evidence of this process occurring, need to amend pre-operative verification section of BSHG 102 Rev 11
Time out immediately prior to surgery	Patient: 1 – immediately before painting and drapes Patient: 2 – immediately prior to painting and draping Patient: 3 - – immediately prior to painting and draping Patient: 4 – immediately prior to painting and draping	Consultant would have conducted time out prior to scrubbing but staff declined to participate Anaesthetist while present did not actively participate.
Consent	Patient: 1 – did refer to consent and confirmed accuracy Patient: 2 – did refer to consent and confirm accuracy Patient: 3 - did refer to consent and	

	<p>confirm accuracy</p> <p>Patient: 4 - did refer to consent and confirm accuracy</p>	
Patient identity	<p>Patient: 1 – Confirmed by checking wrist band and patient notes</p> <p>Patient: 2 - Confirmed by checking wrist band and patient notes</p> <p>Patient: 3 - Confirmed by checking wrist band and patient notes</p> <p>Patient: 4 – Confirmed by checking wrist band and patient notes</p>	
Correct side/site	<p>Patient: 1 – Checked with consent form and markings</p> <p>Patient: 2 – Not applicable</p> <p>Patient: 3 – Operative site marked once positioned</p> <p>Patient: 4 – Checked with consent form and marking</p>	<p>Accordance with policy</p> <p>Marked side pre-operatively and the site at time of positioning</p>
Agreement on procedure	<p>Patient: 1 – Agreement from the team</p> <p>Patient: 2 – Agreement from the team</p> <p>Patient: 3 – Agreement from the team</p> <p>Patient: 4 – Agreement from the team</p>	
<i>Correct Position</i>	<p>Patient: 1 – Position not confirmed</p> <p>Patient: 2 – Position was confirmed</p> <p>Patient: 3 – Position was confirmed</p> <p>Patient: 4 – Position was confirmed</p>	<p>Good reference to previous THR</p> <p>Active participation from consultant</p> <p>Active participation from consultant</p>
<i>Availability of implants etc</i>	<p>Patient: 1 – Mentioned</p> <p>Patient: 2 – Mentioned</p> <p>Patient: 3 – Actively confirmed</p> <p>Patient: 4 – Actively confirmed</p>	
<i>Availability of imaging</i>	<p>Patient: 1 – mentioned</p> <p>Patient: 2 - mentioned</p> <p>Patient: 3 – Displayed</p> <p>Patient: 4 – Displayed</p>	<p>Images displayed and confirmed</p>

<i>Concerns</i>	<p>Patient: 1 – team disbanded before this was completed</p> <p>Patient: 2 – Direct question to anaesthetist, anaesthetist did not actively participate</p> <p>Patient: 3 – Direct question to anaesthetist and actively participated</p> <p>Patient: 4 – Direct question to anaesthetist and actively participated</p>	
<i>Critical events considered</i>	<p>Patient: 1 – discussed between circulating nurse and anaesthetist only – entire team not involved.</p> <p>Patient: 2 - Direct question to anaesthetist, did not actively participate</p> <p>Patient: 3 – Direct question to anaesthetist and actively participated</p> <p>Patient: 4 – Direct question to anaesthetist and actively participated</p>	
Initiated by scrub nurse	<p>Patient: 1 – Initiated by circulating nurse and consultant then took lead.</p> <p>Patient: 2 – Initiated by circulating nurse</p> <p>Patient: 3 – Initiated by anaesthetic nurse</p> <p>Patient: 4 – Initiated by circulating nurse</p>	
Team present	<p>Documentation reviewed – BSHG 106/Rev 11</p> <p>Patient: 1 – all team names were documented and ticked present</p> <p>Patient: 2 - all team names were documented but not marked as present</p> <p>Patient: 3 - all team names were documented but not marked as present</p> <p>Patient: 4 - all team names were documented but not marked as present</p>	
Consent	<p>Patient: 1 – marked as confirmed</p> <p>Patient: 2– marked as confirmed</p> <p>Patient: 3– marked as confirmed</p> <p>Patient: 4– marked as confirmed</p>	
Correct site, patient, position and equipment	<p>Patient: 1 – marked as confirmed</p> <p>Patient: 2 - marked as confirmed</p> <p>Patient: 3– marked as confirmed</p> <p>Patient: 4– marked as confirmed</p>	
Concerns	<p>Patient: 1 - marked as confirmed</p> <p>Patient: 2 – marked as confirmed</p> <p>Patient: 3– marked as confirmed</p> <p>Patient: 4– marked as confirmed</p>	
Sign and time	Patient: 1 – signed and timed	

	<p>Patient : 2 – Signed and timed</p> <p>Patient: 3 – signed and timed but time very difficult to read</p> <p>Patient : 4 – Signed and timed</p>	
Procedure not to start until questions are resolved	<p>Patient: 1 – no discussion on whether ok to proceed.</p> <p>Patient: 2 - no discussion on whether ok to proceed.</p> <p>Patient: 3 – definite confirmation of agreement to proceed.</p> <p>Patient: 4 – definite confirmation of agreement to proceed.</p>	
Training	<p>AOT – While the competency checklist includes sign off on Time out and verification process by CNM 11, the staff member in question has not signed that section of the document. Training occurred on 19/08/2014 but states ‘Discussion on Practices’ (Rev. 2)</p> <p>AS - The competency checklist includes no sign off on Time out and verification process by CNM 11, the staff member in question has signed that section of the document – February 2009 (Rev. 2)</p> <p>MS - The competency checklist includes no sign off on Time out and verification process by CNM 11, the staff member in question has ticked that section of the document –27/09/2010 (Rev. 1).</p>	<p>Review competency documentation for double signatures and date per competency</p> <p>Ensure correct version of document is used</p>

Appendix 4

Pilot Audit Tool

Time Out Pilot – Audit Tool

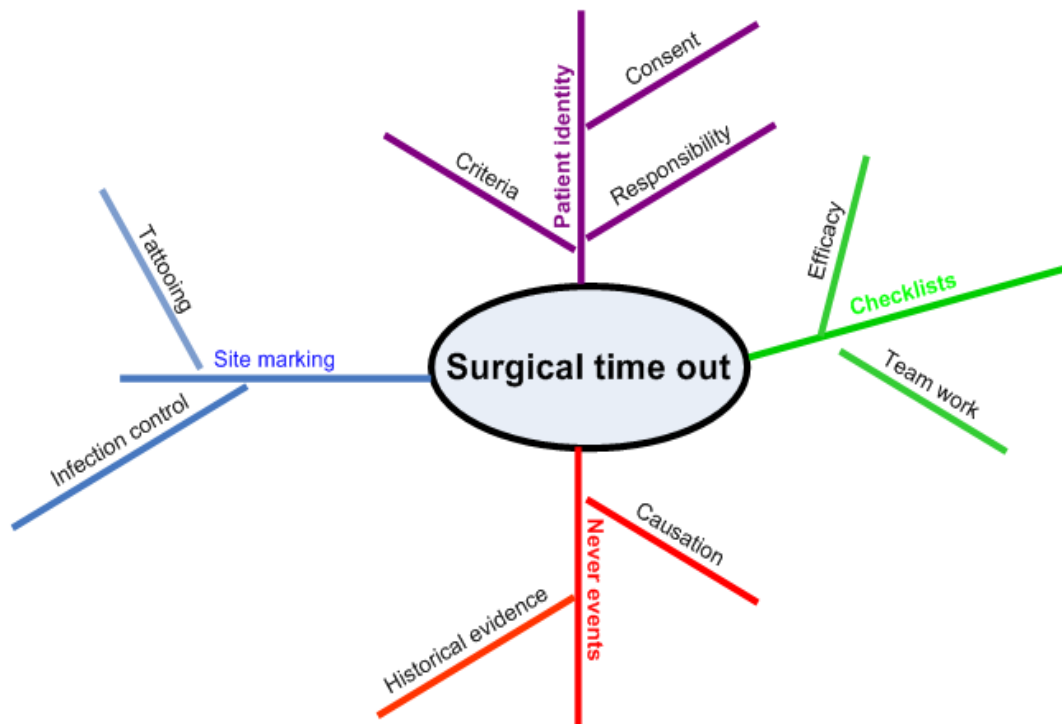
Date: _____ **Speciality:** _____

Number of Patients: _____

	Criteria Hospital No.				
	Procedure				
Before Draping	Verification of Patient/Consultant	S A	S A	S A	S A
	Patient Identity Confirmed	Y N	Y N	Y N	Y N
	Site Mark Confirmed & Visible	Y N	Y N	Y N	Y N
	Side Confirmed	Y N	Y N	Y N	Y N
	Consent for Planned Procedure	Y N	Y N	Y N	Y N
Before knife to skin	Patient Identity Confirmed	Y N	Y N	Y N	Y N
	Site Mark Confirmed & Visible	Y N	Y N	Y N	Y N
	Side Confirmed	Y N	Y N	Y N	Y N
	Consent for Planned Procedure	Y N	Y N	Y N	Y N
	Comments if No				

Appendix 5

Mind Map – Surgical Time Out



Appendix 6

Survey Tool

Time Out Questionnaire

- 1.** Does your hospital have a policy/procedure for Safe Surgery?
Yes No Other (Please specify)
- 2.** If yes to above, has this policy been developed in line with the National Policy and Procedure for Safe Surgery (2013)?
Yes No
- 3.** Does your theatre department use a safe surgery checklist?
- 4.** Please indicate how your department has implemented the checklist.
 - ☐ We have implemented the entire checklist.
 - ☐ We have implemented a modified version of the checklist.
 - ☐ Other – Please specify.
- 5.** Is the consultant or operating surgeon who will be performing the skin incision present for 'Time out'
 - ☐ Always
 - ☐ Usually
 - ☐ Sometimes.
 - ☐ Rarely
 - ☐ Never.
- 6.** Who leads on 'timeout'.
 - ☐ Surgeon
 - ☐ Anaesthetist
 - ☐ Anaesthetic nurse.
 - ☐ Scrub Nurse
 - ☐ Circulating Nurse.
 - ☐ Other.
- 7.** When does surgical timeout occur?
 - ☐ (a) Before painting and draping.
 - ☐ (b) After painting and draping and immediately prior to knife to skin
 - ☐ (c) Either (a) or (b) depending on surgeons preference
 - ☐ Other. Please specify.

8. Is the patient positioned before time out is called?
- ☐ Always
 - ☐ Usually
 - ☐ Sometimes.
 - ☐ Rarely
 - ☐ Never.
9. During timeout how is the patient identity confirmed.
- ☐ By checking the patient's identity bracelet.
 - ☐ By checking the patient's record including consent
 - ☐ By checking the patient identity bracelet and patient consent & record.
 - ☐ Other. Please specify.
10. Can the patient identity band be accessed during timeout.
- ☐ Always
 - ☐ Usually
 - ☐ Sometimes.
 - ☐ Rarely
 - ☐ Never.
11. When necessary is the surgical site mark visible during timeout.
- ☐ Always
 - ☐ Usually
 - ☐ Sometimes.
 - ☐ Rarely
 - ☐ Never.
12. If site mark is not visible during time out is this because:
- ☐ The mark is occluded by the drapes
 - ☐ The mark has been compromised by skin preparation
 - ☐ Both of the above
 - ☐ Other. Please specify.
13. Please indicate the type of organisation.
- ☐ Public HSE Hospital
 - ☐ Private Hospital.
 - ☐ Voluntary Hospital.
 - ☐ Other.

- 14.** Please indicate the number of operating rooms in your department.
1 20

Thank you for taking the time to complete this survey.

Appendix 7

Information Leaflet for Survey



Information Leaflet for Participants

Study title: Pause for thought: Surgical Time Out, before or after draping? A Quality Improvement project.

Surveyors Name: Margaret Mc Hugh

Telephone number: 087 2617156

Dear Colleague,

I am an MSc student in Quality and Safety in Healthcare at the RCSI. As part of my Organisational Development project, I wish to ascertain current practices in Irish hospitals in relation to the implementation of the National Policy and Procedure for Safe Surgery and the timing of Surgical Time Out.

The purpose of this survey is to determine how widely the National Policy has been implemented and when Surgical Time Out is conducted.

In Ireland, the timing of surgical Time Out is not clearly defined. The National Policy and Procedure for Safe Surgery states that while before skin incision is the recommended time to complete the "Time Out" based on the WHO recommendations, if individual organisations wish to perform the "Time Out" prior to skin preparation and draping the patient this may be adapted locally (Quality and Patient Safety Directorate, 2013).

I would welcome and value your participation in this survey. If you consent to participate, a simple survey tool with 11 questions will be forwarded via Survey Monkey in the coming days. Please follow the link to Survey Monkey and complete the survey.

Your participation is voluntary and all responses will be anonymised. Data collected during the survey process will be analysed and frequency statistics will be reported.

This survey will take less than 2minutes to complete. Findings from this survey will be made available on request and I hope will inform quality improvement initiatives in safe surgery practices in the future.

Please find attached information outlining the questions. If you need any further information in relation to this survey, please do not hesitate to contact me.

Margaret McHugh

Name: Margaret McHugh